

A RANDOMIZED CONTROLLED TRIAL COMPARING EQUINE-ASSISTED
THERAPY AND EXERCISE EDUCATION FOR ADULTS
AND OLDER ADULTS WITH ARTHRITIS

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ABSTRACT

Arthritis creates pain, stiffness, and decreased functionality affecting adults' and older adults' quality of life. Equine-assisted therapy provides unique movements to the rider's joints and muscles improving pain, range of motion, and quality of life. No research has investigated the effects of equine-assisted therapy (EAT) on adults and older adults with arthritis. The purpose of this pilot study of a convenient sample was to assess the feasibility and acceptability of conducting a randomized controlled trial comparing an EAT intervention with an exercise education attention (ExEd) control intervention. A review of literature, methods, settings, procedures, results, discussion, limitations, and conclusions are included. This study was registered with clinical trials.gov, approved by the University of Missouri-Kansas City Institutional Review Board, and followed Consolidated Standards of Reporting Trials guidelines. Settings included a Professional Association of Therapeutic Horsemanship International (PATH)-certified riding stables with PATH-certified riding instructors administering the EAT intervention, and Saint Luke's College of Health Sciences for the ExEd attention controlled intervention. Twenty-one consenting participants were randomized and single-blinded to assignment. Dose consisted of a one hour intervention,

once a week for six weeks. Measurements occurred at baseline, three weeks, and six weeks. Outcomes included back, knee, hip, and shoulder pain, and range of motion, quality of life, and enjoyment of nature. Biomarkers measured cartilage and muscle status. Results supported the feasibility and acceptability of the research design, protocol, and methods. Findings indicated significant improvements in back, hip, and shoulder pain, and back and hip range of motion. Quality of life measures had significant improvements over time for upper limb, lower limb, and affect, but not for symptoms and socialization. No significant results were obtained in Cartilage Oligomeric Matrix Protein biomarkers, serum troponin T, and enjoyment of nature. Limitations include small sample size, confounding variables, and threats to validity. The protocols and methods were feasible and acceptable. Continuing EAT after the study was not acceptable. Biomarkers may not be sensitive or specific enough for this research. A tool to assess the barn environment should be developed. Large multi-center trials will provide important generalizable information in future EAT researchers.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the School of Nursing and Health Studies, have examined a dissertation titled “A Randomized Controlled Trial Comparing Equine-Assisted Therapy and Exercise Education for Adults and Older Adults with Arthritis,” presented by Sharon White-Lewis, candidate for the Doctor of Philosophy degree and hereby certify that in their opinion it is worthy of acceptance.

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CONTENTS

ABSTRACT	iii
LIST OF ILLUSTRATIONS	xi
LIST OF TABLES.....	xii
ACKNOWLEDGMENTS	xiii
Chapter	
1. INTRODUCTION	1
Study Purpose and Working Hypothesis	2
Specific Aims/Hypotheses.....	3
Primary Research Questions/Aims	3
Exploratory Questions/Aims	4
2. REVIEW OF LITERATURE	8
Abstract	8
Contributions of the Paper	9
Introduction.....	10
Method.....	12
Measures	13
Results.....	13
Description of Studies.....	13
Design	14
Interventions	15
Control/Comparison	18
Theory.....	18

Dependent Variables.....	19
Measurement.....	20
Outcomes	20
Quality Scoring.....	33
Discussion.....	35
Main Findings	35
Intervention Components.....	37
Theory.....	38
Intervention Frequency and Duration	39
Study Rigor and Study Quality	40
Conclusion	41
3. THEORETICAL FRAMEWORK AND METHODOLOGY	43
Theoretical Framework.....	43
Engel’s Biopsychosocial Model	43
Sub-theories	46
Proposed Conceptual Model for Equine-assisted Therapy Research for Adults with Arthritis	51
Methodology.....	53
Research Design	54
Participants	54
Settings	59
Instruments	60
Procedure	68

Fidelity to Intervention	71
Research Assistant Training	72
Risk Prevention.....	72
Laboratory Procedures.....	74
Data Management.....	75
4. RESULTS	77
Primary Research Questions.....	77
Research Question 1	77
Research Question 2	85
Exploratory Research Questions.....	88
Exploratory Research Question 1	88
Exploratory Research Question 2	89
Exploratory Research Question 3	91
Exploratory Research Question 4	92
Exploratory Research Question 5	93
Exploratory Research Question 6	93
5. DISCUSSION	97
Study Feasibility	97
Securing Facilities and Support Staff	97
Recruitment.....	98
Screening Implementation	99
Intervention Implementation	100
Attrition.....	101

Measurements	102
Acceptability of the Study Protocol.....	103
Dependent Variables.....	103
Pain and ROM	103
Quality of Life	105
Enjoyment of Nature – Environment.....	106
Biomarkers COMP and Troponin T	106
Adverse Events	107
Overall Impressions of the Study	108
Limitations	108
Conclusion	110

Appendix

A. Visual Analog Scale	111
B. AIMS-2 SF Arthritis Impact Measurement Scales 2 Short Form.....	112
C. Engel’s Biopsychosocial Model, Debusse’s Model, and Proposed EAT Model.....	115
D. Equine-Assisted Therapy for Adults and Older Adults with Arthritis EAT Intervention Group Curriculum	118
E. Exercise Training for Adults with Arthritis.....	129
F. Range of Joint Motion Evaluation Chart.....	130
G. Facilities/Support.....	133
H. Opt-in Form	140
I. Screening Tool.....	142
J. Consent Forms	143

K.	H.E.A.T. Study Protocol Impediment/Violation Form.....	158
L.	Exit Surveys.....	159
M.	Engel’s Biopsychosocial Concept – Dependent Variables.....	161
N.	Environmental Attitude Inventory Scale – Enjoyment of Nature	162
O.	Protocol Steps	163
P.	Safety Training	167
Q.	Data Analysis.....	172
	REFERENCES	177
	VITA.....	198

ILLUSTRATIONS

Figure	Page
2.1. PRISMA 2009 Flow Diagram	11
2.2. Tri-Rotational Movement of Equine-assisted Therapy	16
3.1 Engel’s Biopsychosocial Model	44
3.2 Debusse’s Conceptual Framework.....	48
3.3 Proposed Equine-assisted Therapy for Adults and Older Adults Model.....	51
3.4 Block Randomization	57
4.1 Study Enrollment, Allocation, Follow-up, and Analysis Using CONSORT Guidelines	78

TABLES

Table	Page
2.1. Interventional Studies on Equine-assisted Therapy	22
2.2. Summary of Quality Scoring	34
4.1 Sample Demographics	79
4.2 Intervention Dose and Sequencing	81
4.3 EAT Dose and Timing Adherence to Protocol.....	82
4.4 ExEd Dose and Timing Adherence to Protocol.....	83
4.5 Research Question 1 – Feasibility	85
4.6 Research Question 2 – Acceptability.....	87
4.7 Results.....	94

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CHAPTER 1

INTRODUCTION

In the United States arthritis accounts for \$128 billion in lost income and medical costs (Centers for Disease Control and Prevention [CDC], 2013). Incidence of arthritis is increasing due to obesity and the aging population (Bijlsma, Berenbaum, & Lafeber, 2011). Adults (40-65) and older adults (>65) with arthritis experience joint pain, stiffness, damage to their cartilage, and decreased range of motion, particularly in their hips, knees, shoulders, and back (Barten et al., 2015; George et al., 2015; Karjalainen et al., 2001). Healthy People 2020 reports that arthritis has a major effect on a person's quality of life, ability to work, and activities of daily life. The treatment objectives are to decrease joint pain, decrease limitations, and decrease psychological stress (U.S. Department of Health and Human Services, 2014)

Interventions include both pharmacologic and non-pharmacologic approaches. Pharmacologic treatments currently used are opioids (Chaparro et al., 2013) and injections of anti-inflammatory medications, morphine, anesthetics or steroids (Staal, de Bie, De Vet, Hildebrandt, & Nelemans, 2008). The side effects from these medications is reason enough to seek a non-pharmacologic intervention to improve the condition of adults and older adults with arthritis. Non-pharmacologic recommendations include physical conditioning (Schaafsma et al., 2013). Fernandes et al. (2013) published definitive practice recommendations using a biopsychosocial approach, an individualized exercise regime to strengthen leg and hip muscles and improve the range of motion for muscle and joint health. To improve musculoskeletal and functional health, the World Health Organization (2010)

also recommends physical activity, including aerobic physical activity, to improve strength, flexibility, and balance.

An emerging non-pharmacologic intervention to improve physical and psychological issues is equine-assisted therapy (Ratliffe & Sanekane, 2009). Unique movements of the horse translate tri-rotational movements from the horse to the human (Selby & Smith-Osborne, 2013). This targets the spine and hip joints with a movement that is not weight-bearing and has the potential for improvement without joint damage. The earliest recorded use of Equine-assisted Therapy (EAT) as a therapeutic methodology was in the writings of Hippocrates (Bizub, Joy, & Davidson, 2003), when soldiers were cured of illnesses by riding horses.

Currently there are many medical uses for horses, both physical and psychosocial. Previous meta-analyses of horses used to improve cerebral palsy in children provide evidence to support the improvement of physical and neuromuscular connections (Nimer & Lundahl, 2007; Tseng, Chen, & Tam, 2013). Rigorous research is necessary to assess the application of this intervention to multiple disease processes including arthritis. The proposed feasibility and acceptability randomized single-blinded controlled trial will address muscle, cartilage, range of motion, pain, quality of life and environmental effect on arthritis with adults and older adults. This first step will further research that assesses improvements of arthritis symptoms and quality of life.

Study Purpose and Working Hypothesis

The study's purpose is to assess the feasibility and acceptability of a six-week equine-assisted therapy program for adults and older adults with arthritis. The following

includes working hypotheses, specific research questions, and aims. How we defined each independent variable will be discussed in Chapter 3, Methods.

Specific Aims/Hypotheses

Primary Research Questions/Aims

RQ1) Specific Aims: To measure the feasibility of conducting a single-blinded randomized controlled trial for equine-assisted therapy as an experimental intervention and exercise education as an attention-control group.

What is the feasibility of adults and older adults with arthritis attending a six-week equine-assisted therapy intervention compared to an exercise education attention-control intervention?

RQ1a) To what extent can we recruit participants to take part in the study?

RQ1b) To what extent can the intervention procedures be implemented correctly?

RQ1c) To what extent can we maintain adequate fidelity with the intervention?

RQ1d) Does the recruitment procedure sequence produce study participants?

RQ1e) How many potential participants meet exclusion criteria?

RQ1f) What is the attrition rate?

RQ1g) To what extent are the measures completed?

RQ1h) Were the measures able to be performed within the designated time?

RQ1i) Do the participants comply with the intervention?

RQ1j) What is the extent of missing data?

RQ2) Specific Aim: To measure the acceptability of the study protocol with equine-assisted therapy as the intervention and exercise education as the control.

For adults and older adults with arthritis, what is the acceptability of the study protocol with equine-assisted therapy and exercise as the intervention?

- RQ2a) Do the study participants intend to continue the intervention after the end of the study?
- RQ2b) Do the participants stay in the assigned groups, e.g., not want to move from control group to treatment group?
- RQ2c) Do participants know that they are in the treatment group or control group at the end of the study?
- RQ2d) Do the participants feel the time spent per session is too long, too short, or just right?
- RQ2e) Do the participants feel the time spent in the study (six weeks) was too long, too short or just right?
- RQ2f) Do the participants feel the measures were too extensive?
- RQ2g) Any other suggestions for improving the study?

Exploratory Questions/Aims

Exploratory specific aim 1: To measure pain in the equine-assisted therapy group and compare it to the attention-control group of exercise education in adults and older adults with arthritis.

Exploratory research question 1: What is the effect of an equine-assisted therapy intervention compared to an exercise attention-control intervention on pain in adults and older adults with arthritis?

Exploratory hypothesis 1: A six-week equine-assisted therapy program will significantly improve pain in adults and older adults with arthritis compared to an attention-control group receiving exercise education.

Exploratory specific aim 2: To measure range of motion in the equine-assisted therapy group and compare it to range of motion in the attention-control group of exercise education in adults and older adults with arthritis.

Exploratory research question 2: What is the effect of an equine-assisted therapy intervention compared to an exercise attention-control intervention on range of motion in adults and older adults with arthritis?

Exploratory hypothesis 2: A six-week equine-assisted therapy program will significantly improve range of motion in hips, shoulders, knees and back more than an attention-control group receiving an exercise education program in adults and older adults with arthritis.

Exploratory specific aim 3: To measure troponin in the equine-assisted therapy group and compare it to troponin in the attention-control group of exercise education in adults and older adults with arthritis.

Exploratory research question 3: What is the effect of an equine-assisted therapy intervention compared to an exercise attention-control intervention on a troponin biomarker for muscle in adults and older adults with arthritis?

Exploratory hypothesis 3: A six-week equine-assisted therapy program will significantly improve troponin biomarker for muscle more than an attention-control group receiving an exercise education program in adults and older adults with arthritis.

Exploratory specific aim 4: To measure Cartilage Oligomeric Matrix Protein, biomarker for cartilage, in the equine-assisted therapy group and compare it to Cartilage Oligomeric Matrix Protein in the attention-control group of exercise education in adults and older adults with arthritis.

Exploratory research question 4: What is the effect of an equine-assisted therapy intervention compared to an exercise attention-control intervention on Cartilage Oligomeric Matrix Protein biomarker for cartilage in adults and older adults with arthritis?

Exploratory hypothesis 4: A six-week equine-assisted therapy program will significantly improve Cartilage Oligomeric Matrix Protein, biomarker for cartilage, more than an attention-control group receiving an exercise education program in adults and older adults with arthritis.

Exploratory specific aim 5: To measure quality of life in the equine-assisted therapy group and compare it to quality of life in the attention-control group of exercise education in adults and older adults with arthritis.

Exploratory research question 5: What is the effect of an equine-assisted therapy intervention compared to an exercise attention-control intervention on quality of life in adults and older adults with arthritis?

Exploratory hypothesis 5: It is hypothesized that a six-week equine-assisted therapy program will significantly improve the quality of life compared to an attention-control group receiving exercise education in adults and older adults with arthritis compared to exercise education.

Exploratory specific aim 6: To measure enjoyment of nature in the equine-assisted therapy group and compare it to enjoyment in the attention-control group of exercise education in adults and older adults with arthritis.

Exploratory research question 6: What is the effect of an equine-assisted therapy intervention compared to an exercise attention-control intervention on enjoyment of nature in adults and older adults with arthritis?

Exploratory hypothesis 6: It is hypothesized that a six-week equine-assisted therapy program will significantly improve the enjoyment of nature compared to an attention-control group receiving exercise education in adults and older adults with arthritis.

CHAPTER 2

REVIEW OF LITERATURE

Chapter two represents a published systematic review. *Equine-assisted therapy intervention studies targeting physical symptoms in adults: A systematic review* was published in *Applied Nursing Research* (White-Lewis, Russell, Johnson, Cheng, & McClain, 2017).

The reference list from this systematic review is incorporated into the references for the entire dissertation.

Abstract

Background: Equine-assisted therapy is an emerging intervention for symptoms but no comprehensive systematic review has been conducted for physical disabilities in adults.

Objectives: Synthesize evidence on equine-assisted therapy intervention studies for physical disabilities.

Design: A systematic review of all intervention studies using equine-assisted therapy was conducted. Data was extracted and scored by two independent reviewers. Study eligibility: 16 years or older, sample size of five or greater, quasi-experimental or experimental design, intervention research involving a living horse, and published in English.

Data Sources: Databases included: ProQuest, Cumulative Index of Nursing and Allied Health Literature, Education Full Text, Medline, Google Scholar, Educational Resources Information Center, PEDro Database, Directory of Open Access Journals, Cochrane; Psych Info, and Database of Abstract Review and Effects.

Review Methods: PRISMA guidelines with Downs and Black quality scoring were used.

Results: Thirty one intervention studies met inclusion criteria, representing 601 subjects from 10 countries. Adults sample sizes from 7 to 38. Outcomes included gait, stability, quality of life, muscle strength, spasticity, body composition, electroencephalogram, and hormone levels. Significant improvements in 94% of studies using hippotherapy, therapeutic horseback riding, and horse exercise. Methodological limitations included lack of theory (100%), small sample sizes (100%), confounders not reported (100%), no power analysis (94%), no blinding (81%), no randomization (62%), and no control group (29%). The majority of studies lacked external validity, power, and internal validity.

Conclusions: Psychological and physical outcomes for adults with varying diseases were improved with equine-assisted therapy. Quality scoring of intervention studies expose the lack of rigor.

Contributions of the Paper

- What is already known about this topic:
 - Equine-assisted therapy has been an intervention since ancient times as a healing method
 - Meta-analysis of equine-assisted therapies for children delivers strong evidence of improvement in physical and quality of life outcomes
- What this paper adds:
 - This systematic review encompasses all known experimental and quasi-experimental research studies written in English with five or more participants using equine-assisted therapy as an intervention.

- Evidence from this review supports equine-assisted therapy as an internationally administered intervention to improve symptoms from multiple diseases.
- Quality scoring reveals a need for increased rigor, larger sample sizes, and further investigation into equine-assisted therapy as a viable intervention.

Equine-assisted therapy intervention studies targeting physical symptoms in adults:

A systematic review

Introduction

Across the world it is estimated 15% of the population or 1 billion people live with disabilities (World Health Organization, 2011). Over \$19 billion is spent annually in the United States on rehabilitation of people with disabilities associated with multiple sclerosis, stroke, balance deficits, and spinal cord injuries (Centers for Disease Control and Prevention, 2012; Hersh & Fox, 2014; National Spinal Cord Injury Statistical Center, 2015; Noll, 2013). This rehabilitation is attempting to alleviate functional impairment, pain, balance deficits and decreased quality of life (Araujo, Silva, Costa, Pereira, & Safons, 2011; Beinotti, Christofolletti, Correia, & Borges, 2013; Bronson, Brewerton, Ong, Palanca, & Sullivan, 2010; Hammer et al., 2005). Evidence supports the positive effects of equine-assisted therapy for children with disabilities (Benda, McGibbon, & Grant, 2003; McGibbon, Benda, Duncan, & Silkwood-Sherer, 2009) and the psychological well-being of both young and older individuals (Selby & Smith-Osborne, 2013). Equine-assisted therapy is defined as an intervention that uses unique qualities of horses for treatment purposes to improve social, gross motor, and self-help skills in individuals (Ratliffe & Sanekane, 2009).

No published systematic review of equine-assisted therapy intervention studies focusing on physical disabilities in the adult population was found.

The purpose of this systematic review was to synthesize evidence and quality of equine-assisted therapy intervention studies. PRISMA guidelines for systematic review were followed (Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2009).

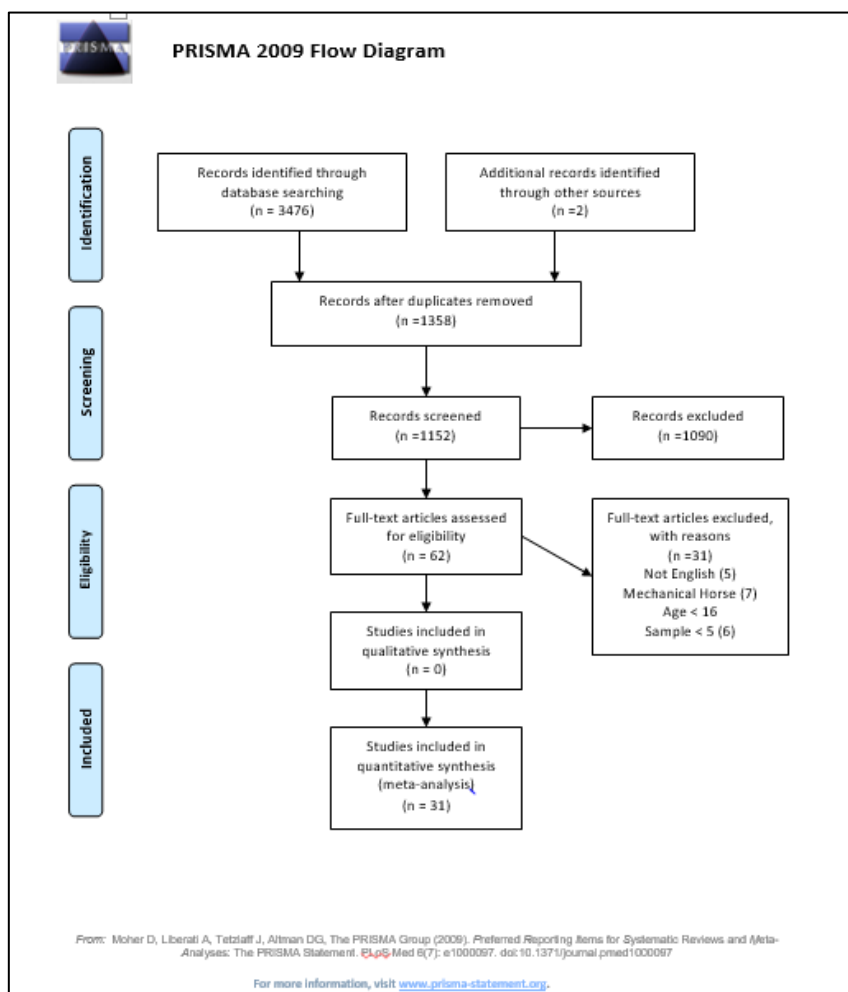


Figure 2.1 PRISMA 2009 Flow Diagram

The following research questions were targeted: What are outcomes of equine-assisted therapy interventions studies in adults? What is the significance of these outcomes? What are various interventions, controls and comparisons that are identified? What is the quality, including internal/external validity, bias, power and reporting? What research designs are reported? What are study strengths and limitations? What theoretical/conceptual frameworks have been used to guide this research? What doses, frequency and duration of equine-assisted interventions have been used?

Method

Data collected included: author/year, purpose, sample, interventions, measures, results, strengths/limitations. The search strategy included searching electronic databases of ProQuest (1872 to 2015), Cumulative Index of Nursing and Allied Health Literature (CINAHL) (1982 to 2015), Education Full Text (1944 to 2015), Medline (1950 to 2015), Google Scholar (2008 to 2015); Educational Resources Information Center (ERIC) (1964 to 2015); PEDro Database (1929 to 2015); Directory of Open Access Journals (DOAJ) (2003 to 2015); Cochrane; Psych Info (1806 to 2015), and Database of Abstract Review and Effects (DARE) (1993 to 2015). The following search terms were used: “equine assisted therapy”; “therapeutic horse riding”; “therapeutic horseback riding”; “hippotherapy”; “equine psychotherapy”; “equine facilitated therapy”; “horse riding for handicapped”, “equus”; “horse therapy”; and “guide horses.” Pet Partner’s (2013) list of equine research articles was accessed and reviewed in May, 2014. Archival searching of reference lists was completed. Study eligibility criteria for this systematic review included: age 16 years of age or older, sample size five or greater, quasi-experimental or experimental design, intervention research involving a living horse or horses, and articles published in English.

Measures

The Checklist for the Assessment of the Methodological Quality of Both Randomized and Non-Randomized Studies of Health Care Interventions-was used (Downs & Black, 1998). This is one of the two most useful tools for quality scoring (Higgins & Green, 2011). The quality domains assessed included: reporting, external validity, internal validity, and power. Data were reviewed and scored by two independent reviewers (S. W. and C. R). Conflicts were communicated and mutually resolved. PRISMA guidelines were followed and reported in the PRSIMA Flow Diagram (see Figure 2.1).

Results

Description of Studies

Thirty one intervention studies met inclusion criteria. A total of 601 participants were included in these 31 studies. Publication dates ranged from 1988 (Brock, 1988; Mackay-Lyons, Conway, & Roberts, 1988) to 2015 (Aranda-Garcia, Iricibar, Planas, Prat-Subirana, & Angulo-Barroso, 2015; Cho, Kim, Kim, & Cho, 2015; Hwang, Lee, & Lee, 2015; Lee, Kim, & An, 2015) with 18 of the studies published since 2012 (Aranda-Garcia et al., 2015; Beinotti et al., 2013; Borioni et al., 2012; Cerulli et al., 2014; de Araújo et al., 2013; Frevel & Mäurer, 2014; T. Homnick, Henning, Swain, & Homnick, 2015; Hwang et al., 2015; H. S. Kim, Lee, & Lee, 2014; S. G. Kim & Lee, 2014; S.-R. Kim et al., 2015; Lee, Kim, & Yong, 2014; Lee et al., 2015; Menezes, Copetti, Wiest, Trevisan, & Silveira, 2013; Sunwoo et al., 2012). Brock (1988) published two studies in the same article. Sample sizes ranged from 7 (Araujo et al., 2011; D. Homnick, Henning, Swain, & Homnick, 2013; Sunwoo et al., 2012) to 38 (Aranda-Garcia et al., 2015). Participants' ages ranged from 16 (Lechner et al., 2003) to 85 years old (Beinotti, Correia, Christofolletti, & Borges, 2010).

Studies were conducted in 10 different countries: Korea (n=8) (Cho et al., 2015; Hwang et al., 2015; H. S. Kim et al., 2014; S. G. Kim & Lee, 2014; S.-R. Kim et al., 2015; Lee et al., 2014, 2015; Sunwoo et al., 2012); the United States (n=7) (Brock, 1988; Farias-Tomaszewski, Jenkins, & Keller, 2001; D. Homnick et al., 2013; T. Homnick, Henning, Swain, & Homnick, 2012; T. Homnick et al., 2015; Silkwood-Sherer & Warmbier, 2007); Brazil (n=4) (Araujo et al., 2011; Beinotti et al., 2010, 2013; de Araújo et al., 2013), ; Germany (n=3) (Boswell, Gusowski, Kaiser, & Flachenecker, 2009; Frevel & Mäurer, 2014; Sager, Drache, Schaar, & Pöhlau, 2008), Italy (n=3) (Borioni et al., 2012; Cerulli et al., 2014; Muñoz-Lasa et al., 2011), Switzerland (n=2) (Lechner et al., 2003; Lechner, Kakebeeke, Hegemann, & Baumberger, 2007). Single studies were conducted in Canada (Mackay-Lyons et al., 1988), Portugal (Menezes et al., 2013), Spain (Aranda-Garcia et al., 2015) and Sweden (Hammer et al., 2005).

Design

Intervention studies targeted the following diseases: multiple sclerosis (19%, n=6/31) (Frevel & Mäurer, 2014; Hammer et al., 2005; Mackay-Lyons et al., 1988; Menezes et al., 2013; Muñoz-Lasa et al., 2011; Silkwood-Sherer & Warmbier, 2007), brain disorders (3%, n=1/31) (Sunwoo et al., 2012), balance deficits (13%, n=4/31) (Araujo et al., 2011; de Araújo et al., 2013; D. Homnick et al., 2013; T. Homnick et al., 2012; S. G. Kim & Lee, 2014), stroke (10%, n=3/31) (Beinotti et al., 2013, 2010; Lee et al., 2014), spinal cord injury (10%, n=3/31) (Farias-Tomaszewski et al., 2001; Lechner et al., 2003, 2007) obesity (3%, n=1/31) (Lee et al., 2015) and breast cancer (3%, n=1/31) (Cerulli et al., 2014).

Designs of the 31 studies included experimental randomized controlled trials (n=12/31; 39%) (Aranda-Garcia et al., 2015; Beinotti et al., 2013, 2010; Boswell et al.,

2009; Brock, 1988b; Cerulli et al., 2014; de Araújo et al., 2013; Frevel & Mäurer, 2014; H. S. Kim et al., 2014; S. G. Kim & Lee, 2014; S.R. Kim et al., 2015; Lechner et al., 2007; Lee et al., 2014, 2015) with 7 of these 12 studies single blinded (58%) (Aranda-Garcia et al., 2015; Beinotti et al., 2013; Borioni et al., 2012; Boswell et al., 2009; T. Homnick et al., 2012, 2015; Lechner et al., 2007).

Nineteen of 31 were quasi-experimental (61%) with 10 of these 19 studies non-randomized controlled trials (53%) (Araujo et al., 2011; Beinotti et al., 2010; Cho et al., 2015; T. Homnick et al., 2012, 2015; Hwang et al., 2015; S.-R. Kim et al., 2015; Menezes et al., 2013; Muñoz-Lasa et al., 2011; Silkwood-Sherer & Warmbier, 2007). Two of these 19 studies used an A-B-A experimental format (11%) (Hammer et al., 2005; Sager et al., 2008). The remaining six of these 19 studies were single group pre-test post-test studies (32%) (Brock, 1988a; Farias-Tomaszewski et al., 2001; D. Homnick et al., 2013; Lechner et al., 2003; Mackay-Lyons et al., 1988; Sunwoo et al., 2012). Brock (1988) included two studies in one citation since both studies were reported in the same article.

Interventions

Treatment interventions were diverse, ranging from standard hippotherapy programs in 14 studies (45%) (Araujo et al., 2011; Beinotti et al., 2010; Borioni et al., 2012; Boswell et al., 2009; de Araújo et al., 2013; Frevel & Mäurer, 2014; S. G. Kim & Lee, 2014; Lechner et al., 2003, 2007; Lee et al., 2014; Menezes et al., 2013; Sager et al., 2008; Silkwood-Sherer & Warmbier, 2007; Sunwoo et al., 2012); therapeutic horseback riding in 10 studies (32%) (Beinotti et al., 2013; Brock, 1988a; Brock, 1988b; Cerulli et al., 2014; Farias-Tomaszewski et al., 2001; D. Homnick et al., 2013; T. Homnick et al., 2012, 2015; Mackay-Lyons et al., 1988; Muñoz-Lasa et al., 2011), and horse exercise in 6 studies (19%) (Aranda-

Garcia et al., 2015; Cho et al., 2015; Hwang et al., 2015; H. S. Kim et al., 2014; S.-R. Kim et al., 2015; Lee et al., 2015).

A standard hippotherapy session, used by the majority of the studies, included a participant mounted on a living horse led by a horse leader. The goal of these hippotherapy sessions was to improve motor function, not to develop equestrian skills (Ratliffe & Sanekane, 2009). A typical horse rider sits astride a horse in the forward position. With this intervention the rider may sit backwards, sideways or lie down on the horse's back. For safety during hippotherapy, two people walked on either side of the horse balancing the participant. The horse's movements dynamically challenged the rider with a tri-rotational movement of their pelvis, hips, legs and spine (see Figure 2.2). The person riding was guided by a licensed therapist to reach, stretch and perform postural changes.

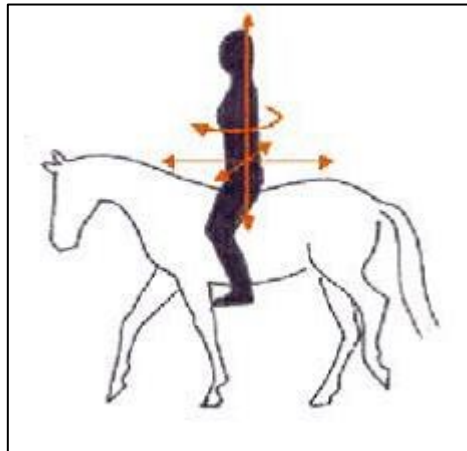


Figure 2.2 Tri-Rotational Movement of Equine-assisted Therapy

Therapeutic horseback riding, used by 35% of the studies, was more independent than hippotherapy and concentrated on introducing the participant to, or improving, horseback riding with therapy as a result of the dynamics of riding. No licensed therapist was involved in this approach. Many times a certified therapeutic riding instructor not

licensed by the state but certified by Professional Association of Therapeutic Horsemanship International directed the intervention. Therapeutic riding differs from hippotherapy by incorporating care, grooming, and saddling. Horse exercise, used by 19% of the studies, was riding without a therapist or a certified instructor. One study used hippotherapy and therapeutic riding terms interchangeably (Hammer et al., 2005).

For all the studies, horse gaits included walking which is a relaxed four beat movement of the horse or walking and then trotting which increased the difficulty and velocity of the horse's movements. Trotting was mentioned in five of the studies (16%) and either not mentioned or the horse was kept at a walk for the remaining sessions (83%). Trotting as a variable was not studied and so its effect cannot be assessed. No cantering was reported. Eight studies (26%) included weaving through cones and obstacles, incorporated stretching or trunk/arm movements and grooming (Aranda-Garcia et al., 2015; Brock, 1988; Cerulli et al., 2014; D. Homnick et al., 2013; T. Homnick et al., 2015; Lee et al., 2015; Menezes et al., 2013). Hippotherapy and therapeutic riding both included stretching before horse riding.

The intervention "dosage" ranged from 15 minutes (S.R. Kim, 2014) to 120 minutes (Brock, 1988) in length. One study did not address intervention "dosage" (Beinotti et al., 2010). Frequency of intervention delivery varied from one (Beinotti et al., 2010; Boswell et al., 2009; Hammer et al., 2005; D. Homnick et al., 2013; T. Homnick et al., 2012, 2015; S. R. Kim et al., 2015; Muñoz-Lasa et al., 2011; Silkwood-Sherer & Warmbier, 2007) to three times per week (Beinotti et al., 2013; H. S. Kim et al., 2014; S.R. Kim et al., 2015; Lee et al., 2014, 2015). The duration of the interventions ranged from 3 weeks (Boswell et al., 2009) to 16 weeks (Aranda-Garcia et al., 2015; Beinotti et al., 2010, 2013; Cerulli et al.,

2014). Five of 31 (16%) studies conducted follow-up assessments after a period of time lapsed with no intervention to evaluate maintenance of improved outcomes (Aranda-Garcia et al., 2015; Borioni et al., 2012; Hammer et al., 2005; D. Homnick et al., 2013; Sunwoo et al., 2012).

Control/Comparison

Control or comparison interventions were diverse. They involved: no additional physical activity or intervention (29%, n=9) (Aranda-Garcia et al., 2015; Araujo et al., 2011; Cerulli et al., 2014; de Araújo et al., 2013; T. Homnick et al., 2012, 2015; Hwang et al., 2015; S.R. Kim et al., 2015; Lechner et al., 2007); conventional physiotherapy (13% n=4) (Beinotti et al., 2013, 2010; Boswell et al., 2009; Muñoz-Lasa et al., 2011); not reported (13%, n=4) (Brock, 1988; Cho et al., 2015; Menezes et al., 2013; Silkwood-Sherer & Warmbier, 2007); treadmill walking (6%, n=2) (S. G. Kim & Lee, 2014; Lee et al., 2014); moderate to vigorous/trunk stability exercise (6%, n=2) (Aranda-Garcia et al., 2015); riding donkey (3%, n=1) (Borioni et al., 2012); walking with stretching (3%, n=1) (Lee et al., 2015); or internet exercise (3%, n=1) (Frevel & Mäurer, 2014).

Theory

No studies used theory as a study foundation. Two authors mentioned theories: Sunwoo (2012) reported that hippotherapy had a theoretical background of motor learning and control. Farias-Tomaszewski et al. (2001) introduced Bandura's Social Cognitive Theory specifically focusing on the concept of self-efficacy and how self-efficacy improves from therapeutic riding successes. Neither author tested these theories or used them as theoretical frameworks for equine-assisted therapy interventions.

Dependent Variables

The primary dependent variables' measures for equine-assisted therapy interventions focused on 9 concepts: balance (55%, n=17) (Aranda-Garcia et al., 2015; Araujo et al., 2011; Beinotti et al., 2010; de Araújo et al., 2013; Frevel & Mäurer, 2014; Hammer et al., 2005; D. Homnick et al., 2013; T. Homnick et al., 2012, 2015; Hwang et al., 2015; H. S. Kim et al., 2014; S. G. Kim & Lee, 2014; Lee et al., 2014; Muñoz-Lasa et al., 2011; Sager et al., 2008; Silkwood-Sherer & Warmbier, 2007; Sunwoo et al., 2012), cadence, speed and stride of gait (39%, n= 12) (Aranda-Garcia et al., 2015; Beinotti et al., 2013, 2010; Boswell et al., 2009; Frevel & Mäurer, 2014; Hammer et al., 2005; S. G. Kim & Lee, 2014; Lee et al., 2014, 2015; Mackay-Lyons et al., 1988; Muñoz-Lasa et al., 2011; Sunwoo et al., 2012), stability (23%, n=7) (Araujo et al., 2011; Hammer et al., 2005; Lechner et al., 2003, 2007; Mackay-Lyons et al., 1988; Menezes et al., 2013), quality of life/self-efficacy/well-being (35%, n=11) (Beinotti et al., 2013; Borioni et al., 2012; Cerulli et al., 2014; Farias-Tomaszewski et al., 2001; Frevel & Mäurer, 2014; Hammer et al., 2005; D. Homnick et al., 2013; Lechner et al., 2007; Mackay-Lyons et al., 1988; Sager et al., 2008; Sunwoo et al., 2012), spasticity (16%, n=5) (Boswell et al., 2009; Hammer et al., 2005; Lechner et al., 2003; Sager et al., 2008), muscle strength/electromyography (13%, n=4) (Aranda-Garcia et al., 2015; Beinotti et al., 2010; Cerulli et al., 2014; Hwang et al., 2015), and body composition (10%, n=3) (Aranda-Garcia et al., 2015; Cerulli et al., 2014; Lee et al., 2015). Hormone levels were measured in one study (3%, n=1) (Cho, Kim, Kim, & Cho, 2015); electroencephalogram was also only measured on one study (3%, n=1) (S. R. Kim et al., 2015).

Measurement

Measurement tools were varied. Three measures used most frequently were the Berg Balance Scale (32%, n=10) (Beinotti et al., 2010; de Araújo et al., 2013; Frevel & Mäurer, 2014; Hammer et al., 2005; T. Homnick et al., 2012, 2015; Lee et al., 2014; Sager et al., 2008; Silkwood-Sherer & Warmbier, 2007; Sunwoo et al., 2012), the Timed-Up-and-Go Test (16%, n=5) (Araujo et al., 2011; Boswell et al., 2009; de Araújo et al., 2013; Frevel & Mäurer, 2014; Hammer et al., 2005) and a force platform (13%, n=4) (Aranda-Garcia et al., 2015; Araujo et al., 2011; Mackay-Lyons et al., 1988; Menezes et al., 2013; Muñoz-Lasa et al., 2011), all used to measure balance. These measures were valid and reliable. Each measure used is listed in Table 2.1.

Outcomes

Statistically significant improvements in one or more main outcomes were noted in 29 of the 31 studies reviewed (94%). Balance improved significantly in 82% of the studies (n=14/17) (Aranda-Garcia et al., 2015; Araujo et al., 2011; Beinotti et al., 2010; de Araújo et al., 2013; Frevel & Mäurer, 2014; Hammer et al., 2005; D. Homnick et al., 2013; T. Homnick et al., 2012; Hwang et al., 2015; H. S. Kim et al., 2014; S. G. Kim & Lee, 2014; Lee et al., 2014; Muñoz-Lasa et al., 2011; Sager et al., 2008; Silkwood-Sherer & Warmbier, 2007; Sunwoo et al., 2012), with quality of life/self-efficacy/well-being improving in 91% of the studies (n=10/11) (Beinotti et al., 2013; Brock, 1988; Cerulli et al., 2014; Farias-Tomaszewski et al., 2001; Frevel & Mäurer, 2014; D. Homnick et al., 2013; Lechner et al., 2007; Mackay-Lyons et al., 1988; Sager et al., 2008). Cadence, gait and stride significantly improved in 80% (n=8/10) (Beinotti et al., 2013, 2010; Frevel & Mäurer, 2014; S. G. Kim & Lee, 2014; Lee et al., 2014, 2015; Mackay-Lyons et al., 1988; Muñoz-Lasa et al., 2011),

stability improved in 83% (n=5/6) (Araujo et al., 2011; Hwang et al., 2015; S. G. Kim & Lee, 2014; Lechner et al., 2003, 2007; Menezes et al., 2013) and muscle strength/coordination also improved (75%, n= 6/8) (Aranda-Garcia et al., 2015; Cerulli et al., 2014; Frevel & Mäurer, 2014; Hammer et al., 2005; Hwang et al., 2015; Lechner et al., 2003). Spasticity improved significantly (80%, n = 4/5) (Boswell et al., 2009; Lechner et al., 2003, 2007; Sager et al., 2008) while body composition (measured by Body Mass Index) significantly improved with exercise in all of the studies (100%, n=3/3) (Aranda-Garcia et al., 2015; Cerulli et al., 2014; Lee et al., 2015). A summary of author, purpose, population, intervention, measures and results are located in Table 2.1.

Table 2.1

Intervention Studies on Equine-assisted Therapy

Author/ Year	Purpose/ Population	Intervention	Measures	Results
Aranda- Garcia et al. (2015)	Physical function -older participants Design: RCT N = 54 enrolled 38 completed	Intervention: 60 minute 3 times/week a)Traditional Exercise b)Horse Exercise c)Control: normal activity	Tools: Gait speed Dynamometer Force platform	Primary: <i>Gait Speed:</i> Horse Exercise (p=0.036)+; Traditional Exercise and Control Group (p not reported)- <i>Muscle strength:</i> Hand grip: Traditional Exercise and Control Group (p=0.47)+; Horse Exercise (p not reported)- Knee extensor 90 ⁰ : Traditional Exercise and Horse Exercise(p=0.13)+; Control Group (p not reported)- <i>Body Balance:</i> Peak Velocity in medial-lateral: Horse Exercise balance worsened in Dual Task (counting backwards and riding); Traditional Exercise and Control Group - same as baseline <i>Body Composition:</i> Traditional Exercise and Horse Exercise (p<0.001)+ Control Group-; Follow Up - all groups (p=<0.001)+
Araujo et al., 2011	Balance - elderly Design: Non- random controlled trial N = 17 enrolled	Intervention: 30 minute bi-weekly a)Experimental Group: Equine assisted therapy/hippother- apy: walk/trot b) Control Group: normal activity	Tools: Force platform Timed Up and Go Test	Primary: <i>Stabalometric data:</i> Between groups: Force platform (p not reported)- Intra-group comparison: anterior/posterior variables (p=0.02)+ <i>Timed Up Go:</i> Between groups: (p=0.04)+ Intra-group: Experimental Group (p=0.04)+;Control Group (p=0.08)-

Author/ Year	Purpose/ Population	Intervention	Measures	Results
Beinotti et al., 2010	Gait training - hemiparetic post-stroke Design: Non-randomized controlled trial N = 20 enrolled	Intervention: a)Experimental Group conventional therapy: 2X/week plus hippotherapy 1X/week b)Control Group: conventional treatment 3 X/week	Tools: Functional Ambulation Scale Fugl-Meyer Scale Berg Balance Scale Functional assessment of gait (cadence)	Primary: <i>FAC time</i> : Intra-group(p=0.0519)-; Between groups (p=0.93)+ <i>Fugl-Meyer</i> : Symptoms motor impairment lower limbs (p=0.01)+ Intra-group: Experimental Group (p=0.004)+; Control Group (p=1.000)- Between groups: (p=0.01)+ <i>Berg Balance Scale</i> : Total study subjects (p=0.007)+ Between groups: (p=0.056)- <i>Cadence</i> : total (p=0.69)-;Between groups: (p=0.19)-
Beinotti et al., 2013	Quality of life-hemiparesis post stroke Design: RCT N = 24 enrolled 20 completed	Intervention: 50 minute physiotherapy 3 times/week. a)Experimental Group: 30 minute therapeutic riding added b)Control Group-conventional therapy	Tool: Medical Outcomes Study – Measures 36	Primary: <i>Outcomes Study Measure 36</i> : Experimental Group (p=0.004)+ Secondary: Subdomains: Functional capacity (p=0.02)+; Physical aspects (p=0.001)+; Mental health (p=0.04)+; Pain (p=0.58)-; General health state (p=0.11)-; Vitality (p=0.33)-; Emotional aspects (p=0.32)-
Borioni et al., 2012	Physical/psycho-social - intellectual disability subjects Design: Non-randomized controlled trial N = 23	Intervention: Dosage not reported a)Hippotherapy b)Onotherapy (donkeys)	Tools: Tool A and Tool B. Equine:Tool A- 68 items Ono:Tool A- 60 items Tool B -13 items	Primary: <i>Psychologists</i> : Autonomy: (p=0.001)+; motor praxis (p=0.035)+; affective-relational (p<0.001)+; cognitive (p<0.001)+ <i>Instructors</i> : Autonomy (p<0.001)+; affective-relational (p=0.002)+; cognitive (p<0.001)+ Psychological pertinence (p<0.001)+; communication (p=1.000)- Ono therapy: statistical improvement in all areas (p not reported) except motor-praxis (p=0.103)-

Author/ Year	Purpose/ Population	Intervention	Measures	Results
Boswell et al., 2009	Multiple sclerosis- adults Design: RCT N =29	Intervention: 20 minutes 1X/ week a)Experimental Group: hippotherapy b)Control Group: additional physiotherapy 1X/ week	Tools: 6/10 minute walking Timed Up and Go Rivermead Tinetti-Test (gait/balance) ARAT (gait analysis) MSSS-88 (spasticity) WEIMuS (fatigue)	Primary: <i>Revermead, Tinetti Test, Gait Analysis, & Spasticity:</i> Intra-group: Both groups had significant improvement (p not reported) Between groups: Hippotherapy significantly improved in gait parameters (p not reported) <i>Timed Up and Go, 6/10 minute walking test & Fatigue:</i> Not reported
Brock, 1988 Study A (Both studies reported in same journal article)	Self-concept, coordination, strength- disabled adults Design: Single group pretest posttest N = 15	Intervention: Therapeutic Riding 60 minutes/week - 90-120 minutes/weekend: 2X/week	Tools: Tennessee Self- Concept Scale Strength/Coordi nation Instrument	Primary: <i>Strength/coordination:</i> Arm and leg coordination (p<0.01)+ <i>Strength and Self Concept:</i> Improvement (p not reported) Reported both studies A and B without differentiating results
Brock, 1988 Study B (Both studies reported in same journal article)	Self-concept, coordination, strength- disabled adults Design: RCT N = 24	Intervention: a)Experimental Group: Riding 60 minutes/week - 90-120 minutes/weekend: 2X/week b)Control Group: not reported	Tools: Tennessee Self- Concept Scale Strength/Coordi nation Instrument	Primary: <i>Strength/coordination:</i> Arm and leg coordination (p<0.01)+ <i>Strength and Self-Concept:</i> Improvement (p not reported) Reported both studies without differentiating results
Cerulli et al., 2014	Psychological/p hysical	Intervention: 2-60 minutes/week	Tools:	Primary:

Author/ Year	Purpose/ Population	Intervention	Measures	Results
	effects - breast cancer survivors Design: RCT N = 20 enrolled 20 completed	a)Experimental Group: Therapeutic riding b)Control Group: Usual care	VO ₂ MAX (cardiac fitness) Body Composition Bioelectrical impedance test Inertial measurement system (strength) FACIT-F (quality of life)	<i>Cardiac Fitness</i> : Main effect for time (p < 0.05)+; interaction (p=0.001)+; intervention group (p<0.001)+ Control Group (p= 0.572)- <i>Body Composition</i> : Fat mass percentage in time (p=0.010)+; Between groups and time (p=0.001)+; intervention group (p=0.002)+; Control Group (p=0.221)- Total body water percentages time p= 0.020+; Interaction p=0.15- Experimental Group (p=0.027)+; Control Group (p=0.585)- <i>Maximal strength principal muscle groups</i> : time (p=0.156; 0.042; 0.018; 0.008; 0.156)+; Interaction effect for group by time (p=0.0005; 0.037; <0.001; 0.017; 0.005)+ <i>Quality of Life</i> : Main effect interaction fatigue (p=0.013)+, General (p=0.025)+; physical, social, emotional, functional total (p=0.020)+
Cho et al., 2015	Hormone levels -elderly Design: Non- randomized Controlled Trial N = 20	Intervention: a)Experimental Group:5 minute riding exercises- walk b)Control Group: not reported	Tools: Serotonin levels Cortisol levels	Primary: <i>Serotonin and Cortisol Levels</i> : Intra-group: Experimental Group: (p<0.05)+; Control Group: (p not reported)- Between groups (p<0.05)+
de Araújo et al., 2013	Functional mobility, muscle strength, balance - elderly Design: RCT N = 28	Intervention: 30 minute bi-weekly a) Experimental group Hippotherapy b)Control Group: normal activities	Tools: Berg Balance Scale Timed Up and Go Test Chair Stand Test	Primary: <i>Berg Balance Scale</i> : Between Groups: (p=0.003)+ <i>Chair Stand Test</i> : Between Groups: (p=0.032)+ <i>Timed Up and Go</i> : Between Groups (p= 0.067)-

Author/ Year	Purpose/ Population	Intervention	Measures	Results
Farias- Tomaszewski et al., 2001	Effect -Spinal cord injury; Cerebral palsy; Scoliosis Design: Single group pretest posttest N = 22	Intervention: Therapeutic Riding: 1 hour sessions	Tools: Scales: Self- efficacy Physical Self- efficacy Global Self- efficacy Behavioral Rating	Primary: <i>Self-efficacy Scale</i> : Main effect of time(p=0.006)+ <i>Physical Self-efficacy Scale</i> : Physical self-efficacy over time (p=0.04)+ <i>Behavioral Rating Scale</i> : (p=0.13)+ <i>Global Self-efficacy Scale</i> : (p=0.93)-
Frevel & Mäurer, 2014	Balance- multiple sclerosis Design: RCT N = 18 enrolled 16 completed	Intervention: a) Experimental group: Internet exercises 2X/week - 45 minutes b)Control Group: Therapeutic riding 2X/week - 20-30 minutes	Tools: Berg Balance Scale Dynamic Gait Index Dynamometer Timed Up and Go test 2 minute walking test Hamburg Quality of Life Questionnaire in Multiple Sclerosis Fatigue Severity Scale Modified Fatigue Impact Scale	Primary: <i>Berg Balance Scale</i> : Intra-group (p=0.011)+; Between groups: No statistical significance (p not reported) <i>Dynamic Gait Index</i> : Intra-group Experimental Group: (p=0.016)+; Control Group (p=0.11)+ Between groups: No statistical significance (p not reported) Secondary: <i>Dynamometer</i> : Intra-group: Both groups (p>0.05)+ Between groups: No statistical significance (p not reported) <i>2Minute Walking Test</i> : Control Group (p=0.032)+ <i>Timed Up and Go</i> : Intra-group and between groups: No statistical significance (p not reported) <i>Modified Fatigue Impact Scale</i> : Experimental Group: Cognitive subscale (p=0.031)+; Control Group: Improved significantly (p not reported) Between groups: (p=0.012)+ <i>Quality of Life</i> : Experimental: No statistical significance (p not reported); Control group (p=0.026)+; Lower limb (p=0.008)+; Mood (p=0.045)+ compared to baseline.
Hammer et al., 2005	Balance, gait, spasticity, strength,	Intervention: 30 minute Hippotherapy/the	Tools: Berg Balance Scale	Primary: (no p values reported) <i>Berg Balance Scale</i> : Significant changes+ <i>Walking a figure 8</i> : No statistical changes-

Author/ Year	Purpose/ Population	Intervention	Measures	Results
	coordination, pain, muscle tension, activities of daily living, quality of life - multiple sclerosis Design: Single subject A-B- A design N = 13 enrolled 11 completed	rapeutic riding/week	Walking a figure 8 Timed Up and Go Test Ashworth Scale Gait velocity Visual Analog Pain Scale 7 point muscle tension scale Patient Specific Functional Scale	<i>Timed Up and Go Test</i> : Intervention period had statistical changes+ <i>Ashworth Scale</i> : Significant changes+ <i>Gait velocity</i> : Significant changes+ <i>Visual Analog Pain Scale</i> : No significance changes- <i>7 point muscle tension scale</i> : Significant changes+ <i>Patient Specific Functional Scale</i> : No significant changes- Secondary: <i>Berg Balance Scale (shifting weight)</i> : Significant changes+ <i>Berg Balance Scale (Timed able to stand; Sitting on pillow; Time in tandem; & Timed able stand one leg)</i> all had significant changes+
Homnick et. al., 2012	Balance - older adults Design: Non- randomized controlled trial N = 15	Intervention: 45 minutes 1X/week a)Experimental Group Therapeutic riding: walk/trot b)Control Group: usual activities	Tools: Berg Balance Scale Fullerton Advanced Balance Scale	Primary: <i>Berg Balance Scale</i> : Experimental Group (p= 0.12)-; Control Group (p=0.93)- <i>Fullerton Advanced Balance Scale</i> : Experimental Group (p=0.15)-; Control Group (p= 0.15)-
Homnick et al., 2013	Balance/quality of life - older adults Design: Single- group pretest- post-test N = 9 enrolled 7 completed	Intervention: 60 minutes 1X/week a) Experimental Group: Therapeutic riding: walk/trot	Tools: Rand Short Form 36 (quality of life) Fullerton Advanced Balance Scale	Primary: <i>Fullerton Advanced Balance Scale</i> : Observation period: No significant change (p=0.35)-; Intervention period: (p=0.001)+; Follow up period: (p=0.908)- <i>Rand Short Form 36 Quality of Life</i> : Most measures of Quality of Life improved: general health perception improved significantly (p=0.003)+
Homnick et al., 2015	Balance - older adults	Intervention: 45 minutes 1X/week 1 time	Tools: Berg Balance Scale	Primary: <i>Berg Balance Scale</i> :

Author/ Year	Purpose/ Population	Intervention	Measures	Results
	Design: Non-randomized controlled trial N = 15 enrolled 15 completed	a)Experimental Group: Therapeutic riding: walk/trot b)Control Group: usual activities	Fullerton Advanced Balance Scale	Intra-group: Experimental Group (p=0.12)-; Control Group (p=0.93)- Between groups: not reported <i>Fullerton Advanced Balance Scale:</i> Intra-group: Experimental Group (p=0.15)-; Control Group (p=0.15)-
Hwang, Lee, & Lee, 2015	Electromyography leg/balance Design: Non-randomized controlled trial N = 20	Intervention: 3X/week a) Experimental Group: Horse exercise b)Control Group- no exercise	Tools: Electromyography lower extremity Balance: One leg standing test	Primary: <i>Electromyography:</i> Rectus femoris and adductor longus (p<0.05)+ Between groups: Semitendinosus adductor longus, Biceps femoris and Rectus (p<0.5)+ <i>Balance:</i> Intra-group: overall stability (p<0.05)+ Between groups: stability (p<0.5)+
S. G. Kim & Lee, 2014	Static balance/gait - older adults Design: RCT N = 30 enrolled 22 completed	Intervention: 20 minutes 3X/week a)Experimental Group: hippotherapy b)Control Group: treadmill walking	Tools: Balance Performance Monitor (sway) AP1105 (step length/times)	Primary: <i>Sway:</i> Decreased both groups (p < 0.05)+; Experimental Group larger decreases than Control Group (p < 0.05)+ <i>Step length/times:</i> Increased both groups (p < 0.05)
S.R. Kim et al., 2015	Electroencephalograms - elderly Design: Non-randomized Control Trial N = 20 enrolled	Intervention: 15 minutes 3X/week. a)Experimental Group: Horse exercise: walk b)Control Group: no exercise	Tool: Electroencephalogram (alpha waves control presence and focus)	Primary: Electroencephalogram: Intra-group: Experimental Group T3 and P4 domains (p<0.05)+; Control Group P3 domain (p<0.05)+ Between groups F3 domains (p<0.05)+ Faster alpha waves in all horse riding subjects and depressed in all control group subjects

Author/ Year	Purpose/ Population	Intervention	Measures	Results
H. S. Kim et al., 2014	Balance - adults Design: RCT N = 24 enrolled 22 completed	Intervention: 40 minutes 3X/week a)Experimental Group: Horse Exercise;walk/trot b)Control Group: exercises	Tool: Good Balance System	Primary: <i>Good Balance System:</i> Intra-group: Sway decreased both groups (p<0.05)+ Between group: Experimental Group larger decreases than Control Group (p<0.05)+
Lechner et al., 2003	Spasticity - Spinal cord injury Design: Single- group pretest- post-test N = 32 enrolled 32 completed	Intervention: 25-30 minutes: 11 sessions Riding: hippotherapy	Tool: Ashworth Scale (spasticity)	Primary: <i>Ashworth Scale:</i> Muscle tone improved (p < 0.001)+; No statistically significant difference between para and tetraplegic (p=0.4)-
Lechner, et al., 2007	Spasticity/mental well-being - spinal cord injury Design: RCT N = 12 enrolled 11 completed	Intervention: Rotating 3 groups - 4 week: 25 minutes 2X/week a)Experimental Group: Hippotherapy; sitting on Bobath roll; sitting on stool b)Control – 4 week non-intervention period	Tools: Ashworth Scale (spasticity) Visual Analog Scale (pain) Befindlichkeits- Skala (well- being scale)	Primary: Short Term Effects <i>Spasticity:</i> Different scores all 4 conditions (p=0.003)+ Intra- groups: Decreased spasticity all 3 Experimental Groups (p=0.004, p=0.003, p=0.005)+; Control Group (p=0.83)- Between groups: Riding and control (p<0.05)+; Bobath roll/stool not significance (no p value reported) <i>Pain:</i> Intra- groups: Riding group, Bobath roll, Control Group (p=0.004, p=0.014; p=0.021)+ Stool sitting (p=0.181)- Between groups: Difference 4 groups (p=0.043)+; Post-hoc difference (p=0.05)+ <i>Well-being:</i> Improved only Riding group (p=0.048)+ Bobath roll and stool (p=0.933 and p=0.497)-

Author/ Year	Purpose/ Population	Intervention	Measures	Results
Lee, Kim, & Yong (2014)	Gait and balance -stroke Design: RCT N = 30	Intervention: 30 minutes 3X/week a) Experimental Group: Hippotherapy b) Control Group: treadmill	Tools: Berg Balance Scale AP1105 (measure gait ability) Step length asymmetry	Primary: <i>Berg Balance Scale, gait velocity and step length asymmetry:</i> Within groups: Experimental Group All improved (p<0.05)+; Control Group improved step length asymmetry (p<0.05)+ Between groups: Improvement Experimental Group over Control Group: gait velocity and step length asymmetry ratio (p<0.05)+ not Berg Balance Scale (p value not reported)
Lee, Kim, & An (2015)	Body Mass Index -obese women Design: RCT N= 24	Intervention: 30 minutes 3X/week a) Experimental Group: Horse exercise: walk/trot b) Control Group: walking/stretching	Tool: AP 1105 (gait analysis)	Primary: <i>Weight:</i> Body mass index: improved (p<0.05)+ <i>Gait Analysis:</i> Intra-group: Both increased step length, width of base (p<0.05)+ Between Groups: Experimental Group larger decrease in BMI; width of base than Control Group (p<0.05)+
Mackay-Lyons et al., 1988	Physical/psychological parameters - multiple sclerosis Design: Single-group pretest-post-test N = 10 enrolled 7 completed	Intervention: 30-45 minutes 2X/week Therapeutic Riding: walk/trot	Tools: Force platform Walkway (speed/stride) SCL-90-R (depression, somatization, global severity)	Primary: <i>Force platform:</i> trend decrease sway not significant (p value not reported) <i>Walkway speed/stride:</i> increased stride length (p=0.008)+, relative speed (p=0.029)+, not stride time (p=0.063)- <i>Depression, somatization, global severity:</i> Depression (p=0.03)+; Global Severity (p=0.05)+; somatization (p=0.32)-
Menezes et al., 2013	Postural control - multiple sclerosis	Intervention: 50 minutes 2X/week a) Experimental Group: Hippotherapy	Tool: Force plate	Primary: <i>Force plate:</i> Between groups: Experimental Group: Postural stability/control improved (p<0.01)+; Control Group:

Author/ Year	Purpose/ Population	Intervention	Measures	Results
	Design: Non-random clinical assay N = 14 enrolled 11 completed	b)Control Group: not reported		not reported. Different sensory conditions both groups (p<0.01)+
Muñoz-Lasa et al., 2011	Balance/gait - multiple sclerosis Design: Non-randomized controlled trial N = 27 enrolled 26 completed	Intervention: 30-40 minute 1X/week a)Experimental Group: Therapeutic riding b)Control Group: physiotherapy	Tools: Extended Disability Scale Modified Barthel Index Force Platform Tinetti Performance (gait and balance)	Primary: <i>Gait and balance</i> : Experimental Group improvement (p<0.005)+ <i>Barthel Index and Extended Disability Scale</i> : Experimental Group: no significant improvement (no p value reported) <i>Stride Time</i> : Experimental Group reduced stride time (p<0.04)+ <i>Gait speed/cadence</i> : Experimental Group: trend to increase (no p reported) <i>Ground reaction force</i> : Significantly increased (p<0.01)
Sager et al., 2008	Balance, spasticity, ability to walk, quality of life- multiple sclerosis Design: Single group A-B-A design	Intervention: 30 minute 2X/week Hippotherapy	Tools: Berg Balance Scale Modified Ashworth (pain, spasm) 10 meter walking test SF-36 (health status)	Primary: <i>Berg Balance Scale</i> : (p=0.002)+ <i>Pain/Spasm</i> : decrease lower extremity (p<0.001)+ <i>Health Status</i> : (p=0.003)+ Secondary: Functional ability (p<0.001)+; physical role function (p=0.007)+; bodily pain (p=0.046)+; vitality (p<0.001)+; social functioning (p=0.009)+; and physical well-being (p=0.004)+
Silkwood-Sherer et al., 2007	Postural instability - multiple sclerosis Design: Single-group pretest post-test	Intervention: 40 minutes weekly Hippotherapy	Tools: Berg Balance Scale Tinetti Performance (gait and balance)	Primary: <i>Berg Balance Scale</i> : Experimental Group increase (p=0.012)+; Control Group no significant changes (p 819)- <i>Gait and Balance</i> : Experimental Group (p=0.006); Control group (p=0.494)- Secondary:

Author/ Year	Purpose/ Population	Intervention	Measures	Results
	N = 15 enrolled 12 completed			Stool touch task: Experimental Group (p= 0.037)+; Control Group had no difference (no p reported)- Between groups: difference pre or midterm (p=0.813 & p=0.204)-; Berg Balance Scale (p=0.043)+; Gait/balance (p=0.07)-
Sunwoo et al., 2012	Effects - brain disorders Design: Single- group pretest post-test N = 8 enrolled 8 completed	Intervention: 30 minute 2X/week Hippotherapy	Tools: Korean Berg Balance Tinetti Performance (gait and balance) 10 meter walking test Functional Ambulatory Korean Beck Depression Inventory Hamilton Depression Rating Scale Modified Barthel Index	Primary <i>Korean Berg Balance, Gait and Balance, Walking: Pre to post (p<0.05)+ Rate of change higher (p<0.05)+ Functional Ambulatory, Korean Beck Depression, Korean Beck Depression, Hamilton Depression Rating Scale, Modified Barthel Index: no difference of any assessments (p not reported).</i>

Quality Scoring

The *Checklist for the Assessment of the Methodological Quality Both of Randomised and Non-Randomised Studies of Health Care Interventions* was used to evaluate methodological quality of the studies (Downs & Black, 1998). The checklist has 27 questions, 26 of which are scored as a 0 or 1 or 2 (0 = does not meet criteria/unable to determine, 1 = meets criteria). One question assessing distribution of confounders had the option of a 0, 1, or 2 (0=does not meet criteria/unable to determine, 1=partially met, and 2=fully met). The checklist total score had acceptable internal consistency reliability (0.89), inter-rater reliability ($r= 0.75$), test-retest reliability (0.88) and was highly correlated with an established instrument that assessed randomized trials ($r= 0.90$) (Downs & Black, 1998). Two reviewers independently critiqued each article with conflicts resolved based on discussion. The few conflicts were discussed and agreed upon at one iterative meeting. Each article was scored by assessing the qualities of reporting, external and internal validity (bias), internal validity (confounding) and power. The power score was separately calculated by one of the authors (bio-statistician A.C.) and was based on the sample size calculation with effect size that was determined from each article, alpha level of 0.05 and preset power level of 70%, 80%, 85%, 90%, 95% and 99%. A summary of the quality scoring results are displayed in Table 2.2.

Table 2.2

Summary of Quality Scoring

Quality Scoring	Reporting	External Validity	Internal Validity - Bias	Internal Validity - Confounding	Power	Total
Possible points	10	3	6	7	1	27
Beinotti, 2013	7	0	6	3	3	19
Aranda-Garcia, 2015	9	1	3	4	0	17
Frevel, 2014	6	0	3	3	5	17
Lechner, 2007	7	0	4	2	0	13
Cerulli, 2014	6	0	3	3	0	12
de Araújo, 2013	6	0	4	2	0	12
Silkwood-Sherer, 2007	8	0	4	0	0	12
Beinotti, 2010	5	0	4	2	0	11
Homnick, 2015	5	0	5	1	0	11
Farias-Tomaszewski, 2001	5	0	4	1	0	10
Homnick, 2012	5	0	4	1	0	10
Hammer, 2005	6	0	3	0	0	9
H. S. Kim, 2014	4	0	3	2	0	9
Lechner, 2003	4	0	4	1	0	9
Muñoz-Lasa, 2011	5	0	3	1	0	9
Araujo, 2011	5	0	2	1	0	8
Homnick, 2013	5	0	3	0	0	8
Lee, 2015	4	0	3	1	0	8
Borioni, 2012	4	0	3	0	0	7
Boswell, 2009	3	0	2	2	0	7
Sunwoo, 2012	4	0	2	1	0	7
S. G. Kim, 2014	4	0	2	0	0	6
Lee, 2014	4	0	2	0	0	6
Mackay-Lyons, 1988	4	0	2	0	0	6
Menezes, 2013	5	0	1	0	0	6
Cho, 2015	3	0	2	0	0	5
Hwang, 2015	3	0	1	1	0	5
S. R. Kim, 2015	3	0	2	0	0	5
Brock, 1988: Study A	2	0	1	1	0	4
Brock, 1988: Study B	2	0	1	1	0	4
Sager, 2008	3	0	1	0	0	4
Total for all studies	156/310	4/93	93/186	41/217	9/31	303/837

Thirty-one studies were reviewed for quality. The quality scoring descriptive statistics include a mean of 8.9, median 8, and mode of 6. Standard deviation is 3.893 with a range of 15 and interquartile range (IQR) of 5. Categories were determined based on the interquartile range with 10 studies scoring poor (IQR score 4-6), 6 scoring fair (IQR 7-8), 8 scoring good (IQR 9-11) and 7 scoring excellent (IQR 12-19). These scores compared only equine-assisted therapy intervention studies. The highest quality study met 70% of criteria with a mean score that met only 33% of criteria. Beinotti et al. (2013) scored the highest with 19/27 points with Aranda-Garcia et al. (2015), and Frevel and Mäurer (2014), both scoring 17/27. The findings decrease sharply after these studies. Overall, reporting scored the highest at 50% with external validity scoring lowest at 0.04% of the possible points.

Discussion

Main Findings

This is the first systematic review to evaluate the body of literature on equine-assisted therapy intervention studies in adults. The most important findings included a statistically significant improvement in outcomes in a majority of studies (94%) with body composition and quality of life most positively affected. Additionally, balance, gait, cadence and stride were statistically significantly improved. These results are suspect since the quality of most of the articles lacked internal, external validity and power which, when compared with ideal research, renders them moderate to weak in quality. Three studies (Aranda-Garcia et al., 2015; Beinotti et al., 2013; Frevel & Mäurer, 2014) were of high enough quality to legitimately claim significant findings of improved physical function, quality of life and balance. The remaining study's positive results were lacking in quality.

More equine-assisted therapy intervention studies have been published in recent years and the rigor is improving over time. The first randomized control trial was conducted in 2007 by Lechner et al. Since then, 11 randomized control trials, 9 in the last two years, have been published. In the equine therapy literature, there have been several systematic reviews and meta-analyses published testing hippotherapy and therapeutic horseback riding interventions with children (Selby & Smith-Osborne, 2013; Sterba, 2007; Tseng et al., 2013; Whalen & Case-Smith, 2012). Statistically significant improvements in gross motor function were found in three reviews (Selby & Smith-Osborne, 2013; Sterba, 2007; Whalen & Case-Smith, 2012) but not the fourth (Tseng et al., 2013). These results are similar to those reported in our systematic review where we have found an 84% improvement in balance and an 80% improvement in cadence, gait and stride.

Bronson et al. (2010) conducted a systematic review of three equine-assisted therapy intervention studies for adults also included in this review (Hammer et al., 2005; Mackay-Lyons et al., 1988; Silkwood-Sherer & Warmbier, 2007). In comparison, our results scored these studies much lower. Bronson et al. (2010) chose to deviate in scoring Hammer et al., (2005) and Mackay-Lyons et al. (1988) criteria as “not applicable” instead of zero (p. 349). Our review awarded zeros on internal validity areas of confounding and bias, resulting in lower scores. Bronson et al. (2010) also did not conduct power analysis in their review, altering the results and scoring these studies higher than our review which did include a power calculation.

The improvement in intervention outcomes with hippotherapy and therapeutic riding may be partially attributed to the barn environment with its outdoor exposure and improvement in quality of life due to the human-animal interaction (Johnson, 2003; Yorke,

Adams, & Coady, 2008). These interventions have a biopsychosocial effect that translates into improvements in body composition, quality of life/self-efficacy/well-being, motor function (cadence, gait, stride) and balance. One proposed reason for the improved motor function is a decrease in spasticity due to the heat of the horse which is one to two degrees higher than humans (Boswell et al., 2009; Hammer et al., 2005; Lechner et al., 2003, 2007)

In opposition to our systematic review's significant findings, Giné-Garriga, Roqué-Fíguls, Coll-Planas, Sitjà-Rabert, and Salvà (2014) analyzed studies in older adults with exercise regimes focusing on flexibility, endurance and strength and found no statistically significant improvements in balance and activities of daily life, whereas the results of our review found statistically significant improvements in both. Finally, Harvey, Lin, Glinsky, and De Wolf (2009) reviewed studies of adults with spinal cord injuries whose interventions included exercise fitness, gait and strength training similar to this review with outcomes targeting range of motion, walking, cadence, and pain. Mixed results were obtained. Issues were consistent with the equine-assisted therapy literature including lack of methodologic rigor (insufficient data by not reporting p values) and inconclusive results.

Intervention Components

The interventions components varied across the reviewed studies. Hippotherapy was used most frequently, followed by therapeutic riding, and horse exercise. One study (Hammer et al., 2005) used both hippotherapy and therapeutic riding interchangeably. Hippotherapy included a licensed medical professional, therapeutic riding included a certified riding instructor who has attended certification classes on equine therapy but does not have a medical background, and horse exercise did not include a professional's guidance. Preference for choosing the intervention components may have been related to

the researcher's background and expertise. Physical therapists, occupational therapists and speech therapists oversaw hippotherapy because it is within their practice domain and would be the intervention of choice as opposed to therapeutic horseback riding which is not a therapeutic modality used in their profession. There was little difference between hippotherapy and therapeutic horseback riding interventions and their influence on statistically significant results. However, all studies using horse exercise reported statistical significance. Horse exercise does not require a licensed medical professional and yet had highly significant outcome improvement. There are no data to support the need for medical professionals to achieve improved outcomes.

Theory

No intervention studies in this review used a theoretical basis for guiding the research methodology. Using a theoretical framework guides research by identifying and organizing concepts and variables so that predictions can be made. According to McEwen and Wills (2014), it "increases the scientific value of a study's findings (p. 400) and enriches the value of those findings" (p. 404).

Theories have been suggested to guide-equine-assisted therapy interventions. Dynamic System's Theory could provide an explanation for the feedback mechanism from the muscles and nerve impulses to the brain associated with hippotherapy (Debusse, Gibb, & Chandler, 2005; Granados & Agis, 2011; Ratliffe & Sanekane, 2009). Motor Learning Theory is another possible theory (Debusse et al., 2009; McGibbon et al., 2009) which posits that learning has set targets, sequences movements for the targets and then transforms them into muscle commands (Willingham, 1998). A third is the Neuronal Group Selection Theory that suggests that a combination of genetics (the subject) and environment (equine-

assisted therapy) with sensory variability could result in improved motor development (Granados & Agis, 2011).

Psychological theories have also been proposed. The psychosocial benefits of equine-assisted therapy are theoretically outlined in Attachment Theory (Bachi, Terkel, & Teichman, 2012). Bachi and colleagues assert that horses provide affect mirroring due to their instantaneous non-verbal feedback to humans. This attribute of human-equine communication produces therapeutic outcomes. The pleasure associated with equine-assisted therapy has been connected to Dynamic Systems Theory by means of the subject interacting with the environment (Granados & Agis, 2011). Attributes of equine assistive activities can be explained by the influence of Robert Weiss' Social Provision Theory (Weiss, 1974) which includes human needs for reliable alliances, and opportunities for nurturance and social integration. McConnell surveyed programs about equine-assisted therapy using grounded theory (McConnell, 2010). She found that Experiential Theory was used most frequently in equine-assisted therapy programs. Klontz, Bivens, Leinart, and Klontz, (2007) and Kolb, Boyatzis, and Mainemelis (1999) agreed that Experiential Theory explained the effectiveness of equine-assisted psychotherapy and that the experiences with the horse produce a therapeutic effect.

Intervention Frequency and Duration

Intervention frequency and duration varied greatly making comparison across studies challenging. Frequency was reported as weekly, twice a week, three times per week, and not reported. The highest frequency was once a week intervention followed by three times a week and then twice a week. The duration was more varied than frequency ranging from 3

weeks (Boswell et al., 2009) to 26 weeks (Muñoz-Lasa et al., 2011). The studies with no significant improvement were not different in these parameters from significant studies.

Five studies assessed subjects after a follow-up period (Aranda-Garcia et al., 2015; Borioni et al., 2012; Hammer et al., 2005; D. Homnick et al., 2013; Sunwoo et al., 2012). This varied from 4 weeks (Hammer et al., 2005) to 18 months (Borioni et al., 2012). In all cases, the participant's balance improvement was maintained during the follow-up period (100%) (Aranda-Garcia et al., 2015; Borioni et al., 2012, D. Homnick et al., 2013; Sunwoo et al., 2012). Hammer et al. (2005) reported no significant maintenance of the changes in spasticity over time.

Study Rigor and Study Quality

When evaluating the studies, the findings indicated the majority were of low quality. The scores were very low in external validity and power. The significant findings of these studies are suspect due to the lack of rigor and quality. The top three studies' were of high enough quality that their findings of improved quality of life, physical function and balance were legitimate. Other lower quality studies also presented these findings but with their lack of quality the results are questionable when translating into clinical practice. Limitations for the studies included small sample size (100%) which could result in a Type II error (Polit & Beck, 2012), lack of random selection (55%) resulting in selection bias (Cochrane Collaboration, 1996) and lack of a control group (29%) which threatens internal validity by introducing confounding variables and decreasing the power of results (Polit & Beck, 2012).

Medication usage and timing by the participants could mask the effect of the intervention on the outcome variables. Medication usage was reported in several studies (24%), but timing of medication effects was not reported in any study. Anti-spasmodic or

anti-inflammatory medication timed so that peak effect occurs during the intervention is a confounding variable and should be reported and calculated.

Conclusion

This manuscript identifies a critical gap in the intervention literature of equine-assisted therapy interventions for adults and provides focus for clinical practice, research, and theory development. Based on the results of this systematic review, there is evidence to support the efficacy of equine-assisted therapy as a beneficial intervention in the adult and older adult population for clinical practice. Balance, spasticity, muscle strength, gait and cadence have been improved with the intervention. Quality of life improvements are also supported. The mechanisms of equine-assisted therapy for improving physical disability include encouraging movement without weight bearing and increased exercise which is equivalent to walking. The improvements are biological, psychological and social which support the biopsychosocial holistic effect of ~~EAT~~ equine-assisted therapy.

These results need to be viewed through a skeptical lens due to poor study quality and rigor. It is encouraging that the rigor of intervention studies is improving. Little mention of fidelity, confounding variable identification and analysis, few articles with power analysis, and no theoretical guidance indicate the need for higher quality research. This will be important for evaluating the effect of this emerging therapeutic technique.

A stronger research design would be to conduct a pilot feasibility and acceptability RCT followed by a fully powered, multi-center RCT adhering to CONSORT guidelines. A power analysis, calculated confidence intervals, and details of demographics, recruitment, assignment, blinding, reasons for attrition, and bias identification should be included. The study should include a theoretical guiding framework. Additionally, a researcher should be

present during outcome measurement sessions to safeguard protocol compliance and increase fidelity. Future research should also be conducted to investigate the enjoyment factor of equine-assisted therapy compared to other standardized exercises.

Studies comparing the components of horse exercise, therapeutic riding and hippotherapy would clarify the intervention parameters. A study on cost benefit would be important for implementation of the intervention for adults and older adults who may find it difficult to travel to a therapeutic equestrian center. Medication timing and interaction effect could moderate the findings and should be accounted for as confounding variables in statistical analyses. Safety and adverse events have not been addressed in the published articles and could be of concern for liability in a large scale application of this therapy.

CHAPTER 3

THEORETICAL FRAMEWORK AND METHODOLOGY

The Horses and Education for Arthritis as Therapy (HEAT) study was guided by theory. This study design is a single-blind, randomized controlled trial in which equine-assisted therapy was compared to exercise education in adults and older adults with arthritis. Section one of this chapter is a discussion of theoretical frameworks that have been connected with EAT. The second section reports the research methods employed in this randomized controlled trial.

Theoretical Framework

In a systematic review of the literature, no intervention studies used theoretical frameworks to guide EAT interventions (White-Lewis, Russell, Johnson, Cheng, & McClain, 2017). The theoretical framework guiding the HEAT study was Engel's Biopsychosocial Model (Engel, 1977). It embraces the physical, psychological, environmental and social influences found in EAT research. Two sub-theories provided additional specific concepts on EAT that were lacking in Engel's model. These two sub-theories are from Debuse and Håkanson (Debuse et al., 2009; Håkanson, Möller, Lindström, & Mattsson, 2009). These sub-theories added the physical, sensory, and psychological effects of EAT and introduced the concept of environmental effects. They are the only other conceptual frameworks found in this immature field.

Engel's Biopsychosocial Model

Engel's (1977) biopsychosocial model is the over-arching theory for the HEAT study (see Figure 3.1). This approach considers the biological, social, and psychological

influences on health, illness, and the delivery of healthcare. The Biopsychosocial Model is particularly useful in directing EAT intervention research targeting arthritis.

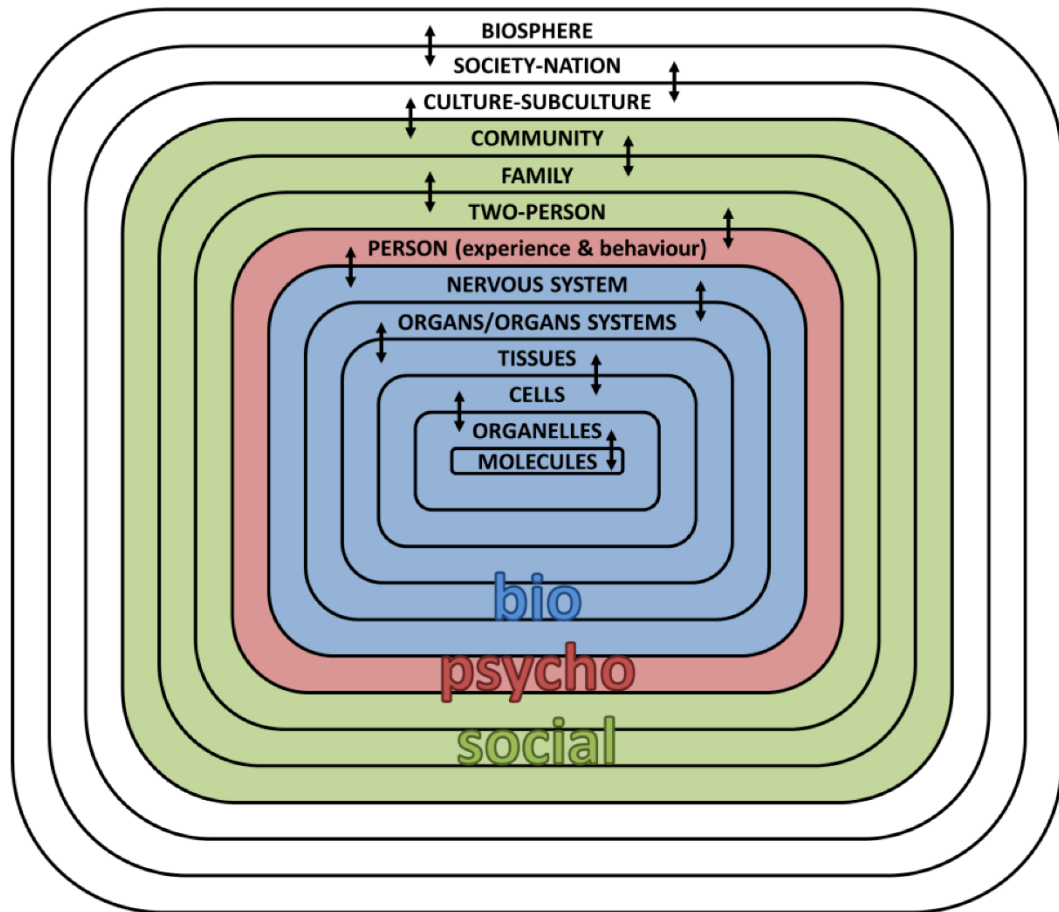


Figure 3.1. Engel's Biopsychosocial Model (Engel, 1980)

This model is consistent with expert recommendations for treating arthritis. The European League Against Rheumatism (EULAR) has provided recommendations on how to manage arthritis since 2007 (Fernandes et al., 2013). Twenty rheumatologists, two patients, and one healthcare professional (not designated) representing twelve countries, formulated non-pharmacological recommendations comprising three overarching principles and twelve recommendations for the diagnosis and treatment of arthritis.

One of the overarching recommendations was to use a holistic biopsychosocial approach to treatment. According to these experts, targeting many aspects of a person's life, rather than focusing in on one medical aspect, is essential for health improvement with arthritis. This is why Engel's (1977) model, which addresses biopsychosocial influences on health issues, guides the HEAT study. Engel (1977) conceptualized a change from the medical model that focused on treating illness, to a model that included the holistic dimensions of illness. He argued that the medical model's primary principle assumed that chemistry and physics can explain biological processes. He contended that relationships between biochemical processes and clinical manifestations of illness required psychosocial and behavioral data to represent the entire clinical picture of a patient's illness. Only by viewing the patient and all aspects that affect that patient can a healthcare provider truly treat the illness. For example, when a person is grieving and has physical, social, and psychological manifestations, would they have a disease? With the medical model, it would be broken into separate manifestations, but only by knowing the whole can the issue truly be treated.

Engel's multi-dimensional approach to treating illness (1981) uses the following assumptions:

- Psychological and physiological processes are closely interrelated.
 - Any imbalance in these processes may lead to ill health.
 - Relationships between psychological and biological variables are generally bidirectional and are central to healthcare delivery.
 - Health outcomes may be altered via appropriately designed interventions
- (Hamilton-West, 2010).

Environment is not specifically mentioned by Engel (1977), but he discussed environmental effects on diabetes, supporting the idea that environment as a variable affects outcomes. No definitions were provided for the varying levels of molecules, organelles, and cells displayed in Engel's model.

Engel's (1977) model begins by identifying influences at the cellular level, then expanding in increments to the biosphere. Following are each level and its corresponding measure in the HEAT study:

- Molecular or cellular level will be evaluated with biomarkers.
- Organ and orthopedic system levels will be assessed with goniometer readings.
- Person level will be assessed by the Primary Investigator (PI) appraising the unique tri-rotational movements of the horse (Selby & Smith-Osborne, 2013) affecting the rider's spine and hip movements.
- Family and community, the next expansion of the model, depict a larger group effect. Support systems are assessed by the social subcategory of the Arthritis Impact Measuring Scale 2 tool (AIMS-2).
- Culture/subculture. The HEAT study will quantify the environmental effect by the Environmental Attitudes Inventory Scale.

This overarching theory does not provide insight into specific EAT effects, so two sub-theories provided guidance in specific EAT areas and are discussed in the following section.

Sub-theories

Debusse. Two conceptual frameworks have been posited for EAT intervention research: one by Debusse et al. (2009) and one by Håkanson et al. (2009). Each provided

unique guidance in conducting EAT research. The first conceptual framework created by Debuse et al. (2009) illustrates a model of the effects of hippotherapy from the patient's perspective (see Figure 3.2). Debuse et al.'s (2009) qualitative study, in which this conceptual model was first introduced, aimed to explore the reality of cerebral palsy afflicted children and adults and the effects of hippotherapy on that reality. She attempted to discover the complex relationship between patient, physiotherapist, horse, and environment. In-depth interviews about the experiences of 17 participants from 4 to 63 years old from Germany and the United Kingdom were included. The researcher identified five themes in the data: context and perception, experiencing the movement, physical effects, psychological effects, and parents' responses to these effects. To ensure rigor, Debuse et al. (2009) used several quality controls including constant comparative analysis and participant verification.

The conceptual framework proposed by Debuse et al. explains interacting effects during hippotherapy (2009). This framework has the following concepts: highly effect motor learning, neuroplasticity, inhibition of abnormal motor patterns, practice of new motor patterns, stimulation of trunk control, immediate enjoyment, situational interest, motivation, increased self-esteem, sense of achievement, and increased parental expectations. The concepts are defined as physical, sensory, and psychological. They are linked together in the following way: a horse's movement creates a neuro-motor stimulation (movement), the horse's body provides sensori-motor stimulation (touch of the fur, smell of the horse, hearing the horse and sounds of the barn, seeing the horse), and the horse's character provides psychomotor stimulation. The horse movement became very tiring for the participants with cerebral palsy, but improvement was seen by the researchers. The participants' muscles showed increased elasticity after hippotherapy. This led to increased

self-esteem and improved confidence in motor movement. Ultimately, this created motivation to attempt new activities.

Debuse et al. (2009) designed a visual model of their conceptual framework to illustrate most of the concepts of EAT (see Figure 3.2), including the interactions between the physical and psychological effects and the holistic effects of equine-assisted therapy. Neuropathways improved with hippotherapy in their study because it mimicked walking by sending impulses to the brain that returned to the muscles supporting joints (Debuse et al., 2009; McGibbon et al., 2009).

The contributions this framework added to the HEAT study include concepts of musculoskeletal movement, quality of life, and improved psychological benefits. This information became the basis for outcome measurements in the HEAT study of range of motion, pain, and stiffness. Debuse et al.'s (2009) conceptual model enhances the HEAT study because it fills the conceptual gaps of the physical effects from the horse. It addresses the improved muscle tone from riding and the psychological effects associated with the sensory input from the environment, including the human-animal relationship. Debuse et al.'s mention of environment as situational interest prompted the HEAT measure of enjoyment of nature. Instead of situational interest that Debuse and associates identified, Engel's theoretical concept of culture/subculture supported the enjoyment of nature (environment) for the HEAT study.

However, Debuse et al.'s (2009) model has some limitations when guiding this research of the effects of EAT for adults and older adults with arthritis. No antecedents or attributes are identified by the author of this model, and linkages to consequences are unclear. These additional characteristics are necessary to fully conceptualize the theory

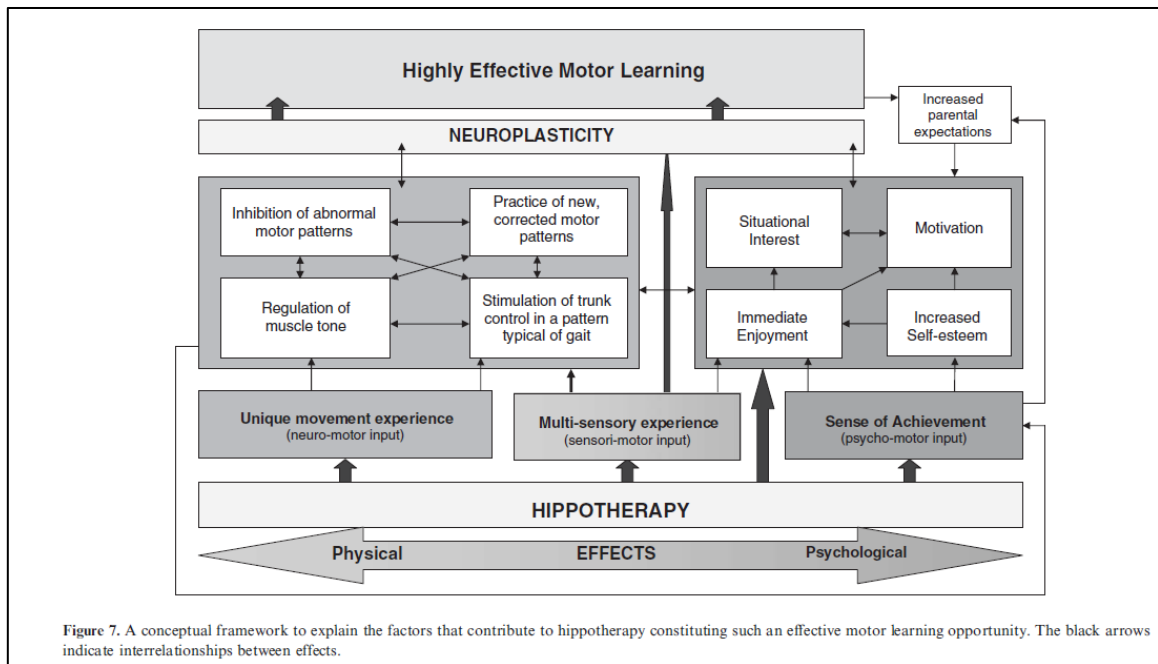


Figure 3.2. Debusé's Conceptual Framework (Debusé et al. 2009)

(Bouso et al., 2014). Also, Debusé et al.'s model does not completely generalize to adults and older adults because the concepts were derived partly from parental qualitative reporting of their children's reactions to hippotherapy. The parental effect and parents' world view of their special needs children do not necessarily translate to adults and older adults with arthritis. Parental effect was not a concept that was needed in this EAT arthritis study. Additionally, this sub-theory does not address the cellular and tissue levels that Engel's (1977) model includes. Debusé et al.'s framework offers a beginning in explaining the many inter-related aspects of EAT but is not necessarily generalizable to the adult.

Håkanson. The only other conceptual framework in physical EAT literature is from Håkanson et al. (2009), who conducted action research of 24 patients with back pain, ages 13-53 years old, to identify if EAT could decrease pain and improve well-being. She conceptualized a sensory, motor influence from the equine-human interaction and she

identified the emotional influence of the horse on the human. This contributed to the HEAT study by identifying the human-horse bond influences, and subsequently a bonding time concept was added to the EAT curriculum. This sub-theory added to EAT research by increasing the body of knowledge associated with EAT. She used the Visual Analogue Scale, which asks the participant to mark on a 100-millimeter line to quantify the perceived feeling of pain (see Appendix A); it was subsequently selected for use in the HEAT study.

From Håkanson et al.'s (2009) model, the following concepts were identified for inclusion in the HEAT study: body awareness, competence, emotion, and environment. Håkanson et al. (2009) was the first to identify environment as a dimension. She attributed this effect to the closeness of nature with new sounds and smells of the barn and animals for participants. With the increased recognition of environmental effect mentioned in the literature (Debusse et al., 2009; Håkanson et al., 2009; Yorke et al., 2008), the effect of the barn environment was added as an outcome measure of enjoyment of nature for the HEAT research study. The smells, textures, and experience of the barn could have been influential and was measured. Also, body awareness and competence, identified by Håkanson et al., was chosen as an outcome in quality of life. The dimension of emotion was assessed via the AIMS-2 self-reporting survey (see Appendix B).

The limitations of using Håkanson et al.'s (2009) conceptual framework in guiding EAT research are that no theory was developed with linkages between concepts, no antecedents or attributes were included, and no generalizability of concepts was presented. Håkanson et al. (2009) did not include a conceptual model when explaining their findings. No theory assumptions were identified in either study. With the lack of fully developed theory features, these were chosen as sub-theories that aided in guiding the HEAT

experimental design and added to the concepts of Engel’s theory in guiding the research, but did not, on their own, fully guide the research.

Proposed Conceptual Model for Equine-assisted Therapy Research for Adults with Arthritis

By combining the strengths of Engel’s theory with those of the two sub-theories above, The Equine-assisted Therapy for Adults and Older Adults conceptual model was created for the HEAT study (See Figure 3.3). Older adults with arthritis have three main choices for treatment: non-pharmacological treatment, pharmacological, and surgical (Fernandes et al., 2013). According to the study conducted by Fernandes et al. (2013), the needs of the older adult with arthritis are education, exercise, weight reduction, and walking aids, if necessary.

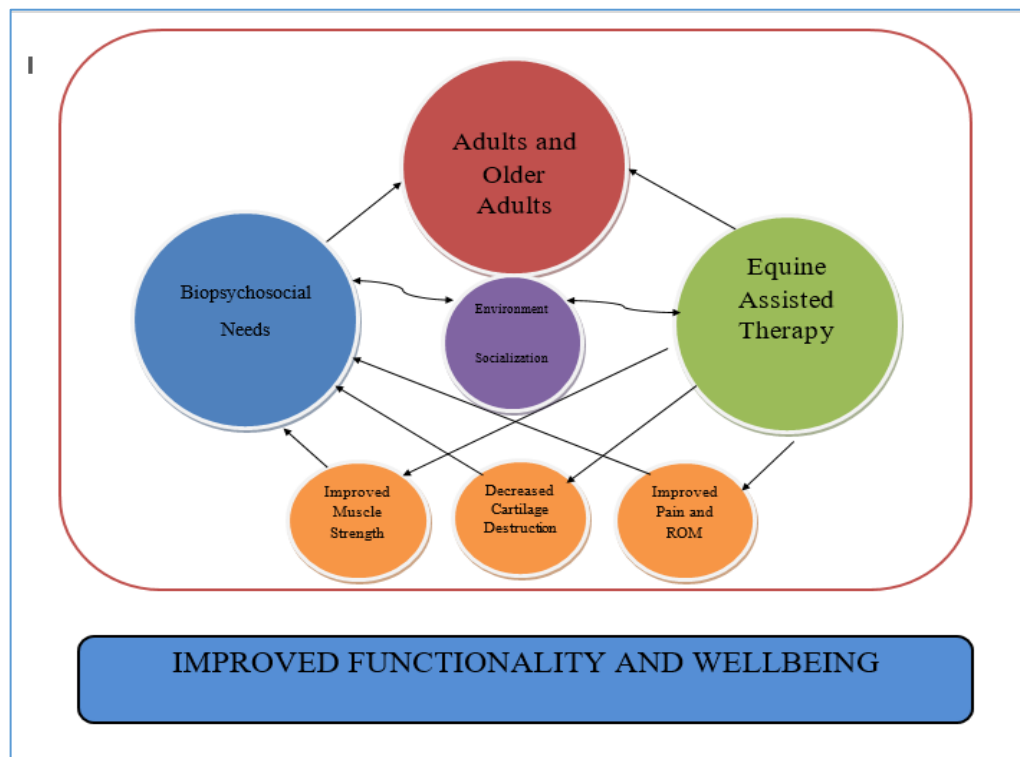


Figure 3.3. Proposed Equine-assisted Therapy for Adults and Older Adults Model

The concepts of this model are defined as physical elements (improved muscle strength, decreased cartilage destruction, improved pain and range of motion); holistic elements (biopsychosocial influences); and contextual elements (environment and socialization). In the model depicted in Figure 3.3, the environment and socialization with staff, horses, and other participants have an effect on the biopsychosocial needs of adults who participate in EAT. Muscle strength, cartilage matrix maintenance, pain, and range of motion (ROM) all may be affected by EAT and thus have an effect on the biopsychosocial needs of the individual. This conceptual model brings together the concepts of biopsychosocial needs, tissue and culture levels identified in Engel's model, equine-assisted therapy effects and motor effects identified in Debusse et al.'s model, and environment and socialization identified in Hakanson et al.'s model.

The equine-human interaction is represented by the EAT circle. The concepts are linked together in the following ways defined by the arrows in Figure 3.3: The improved physical aspects of muscle, cartilage, range of motion, and decreased pain influence the world of the participant in all levels from the cells (by altering the structure of the muscles and cartilage), to the society and culture (effected by socialization and participation in outside activities at the therapeutic center). The horse, through EAT, affects the adult and older adult through contact, environment, and equine-human socialization. These in turn affect the socialization of the biopsychosocial system the participant interacts with a daily basis.

The operational definitions of the constructs represented in the model are improved muscle strength measured by serum troponin, quality of life measured by the Arthritis Impact Measurement Scale² (Meenan, Mason, Anderson, Guccione, & Kazis, 1992), and

decreased cartilage destruction, measured by cartilage biomarkers (Posey & Hecht, 2008). A linkage exists between skeletal muscle, the type of muscle supporting joints and serum troponin levels (Brotto, Biesiadecki, Brotto, Nosek, & Jin, 2006). Since muscular support is important for joint health (Knoop et al., 2012), and people with arthritis exhibit multifactorial issues such as malalignment and abnormal joint forces (Lange et al., 2009), any research to improve joint functionality would include an element of exercise – which is EAT in this model.

In EAT literature, the effect of the barn and environment are frequently mentioned but not measured. Environment affects the biopsychosocial needs and are affected by EAT, and in turn, the biopsychosocial needs alter the environment and EAT. Yorke, Adams, and Coady (2008), who studied the therapeutic effect of the human-equine bond after trauma, stated that the environment of the barn affected the human-animal bond and provided an environment for healing. The equine-human interaction was reflected in the feasibility and acceptability of horses as a therapeutic intervention. The HEAT study assessed the positive or negative effect EAT had on these measures. Further theory development would include antecedents, linkages, attributes, and consequences. Full theory development is not the intent of this study.

All conceptual models are displayed adjacent to each other in Appendix C.

Methodology

The following is a description of the methodology used in the research design, participant recruitment, randomization, and blinding. The Institutional Review Board (IRB) procedures are discussed. Then settings for recruitment of participants and the intervention sites are reviewed. Finally, documentation methods, instrument choices, reliability, and

validity are presented by separating them into study outcome measures of recruitment, feasibility, acceptability, range of motion (ROM), pain, quality of life (QOL), COMP, troponin T, and environment.

Research Design

The research design used in the HEAT study was a feasibility and acceptability single-blind, parallel randomized controlled trial of a convenience sample. The participants were blinded to assignment, and allocation was 1:1. The experimental intervention group included grooming, saddling, and riding a horse for one hour each week for six weeks (see EAT Curriculum in Appendix D) and the attention-control group received exercise education in sessions of the same length, for the same time period and at the same frequency as the schedule of the EAT in the treatment group (see Exercise Training for Adults with Arthritis in Appendix E. Consolidated Standards of Reporting Trials (CONSORT) (Schulz, Altman, & Moher, 2010) were followed, and the study was registered with U.S National Library of Medicine at Clinical Trials.gov. number NCT03141853 (National Institute of Health, 2017).

Participants

The targeted patient population was adults and older adults with arthritis diagnosed by their physician or advanced practice nurse and self-reported to the primary investigator (PI). Inclusion criteria were: (a) written physician's or advanced practice registered nurse's (APRN) clearance to ride a horse; (b) ability to read and understand English as evidenced by the capacity to follow verbal and written directions at the screening interview; (c) pain in one joint: a shoulder, hip, back, or a knee. Pain was measured by the Visual Analog Scale (1-100mm horizontal line), and participants were included with mild [Mild pain (0-44)] to

moderate pain levels [Moderate pain (45-74 mm)] (Hawker, Mian, Kendzerska, & French, 2011); (d) decreased range of motion by 20% or greater, measured by a goniometer, and documented on the Range of Joint Motion Evaluation Chart (see Appendix F; and (e) transportation accessibility to a therapeutic riding center once a week for six weeks. Exclusion criteria were: (a) fear of horses, (b) allergies to horses, (c) self-reported osteoporosis, (d) inability to abduct hips wide enough to straddle a horse comfortably, (e) lack of transportation for the six week study, (f) horse riding in the previous six months, or (g) age younger than 45 years.

Sample size for this pilot study was determined by systematically reviewing 31 intervention studies utilizing equine-assisted therapy for physical disabilities where the sample size mean of these studies was 18.9 participants (White-Lewis, Russell, Johnson, Cheng, & McClain, 2017). As a benchmark, previous EAT pilot studies enrolled: eight (Sunwoo et al., 2012), fifteen (T. Homnick et al., 2015; Silkwood-Sherer & Warmbier, 2007), and twenty (Cerulli et al., 2014) participants. Anticipated attrition was estimated at 20% based on previously published studies' attrition rates, which were 16.6% (Aranda-Garcia et al., 2015; Beinotti et al., 2013), 22% (Homnick, Henning, Swain, & Homnick, 2013), 21% (Menezes et al., 2013), and 20% (Silkwood-Sherer & Warmbier, 2007). Fifty-one adults and older adults were contacted for screening by the PI. Twenty-one consented, and 20 finished the study with an attrition of one participant, which resulted in an attrition rate of 5%.

Recruitment and randomization. Recruitment began July 7, 2017 and finished November 22, 2017. Recruitment continued simultaneously with EAT and education intervention administration until sample targets were attained. Kansas City Physician

Partners' physicians and staff (see Facilities in Appendix G) were educated on the study protocol, study parameters, and identification of potential participants by the PI. A sign was placed by the office personnel in the waiting room of the physicians' offices stating that a non-medication six-week study to help with pain and stiffness of arthritis was recruiting interested participants willing to be contacted for a study. When potential participants inquired about the study, they were given an Opt-In Form by office personnel, physicians, and nurses (see Appendix H). This form provided the PI permission to contact the patient. Once agreement for initial contact was obtained, the PI telephoned the participant and arranged an initial two-hour meeting to review the study protocol and consent form and complete the initial screening protocol.

At the initial screening to assess eligibility for study, the participant was given a screening and demographic survey by the PI (see Appendix I). If the participant met inclusion criteria, the participant was randomly assigned into one of two groups: 1) the intervention group/EAT group, or 2) the attention control exercise education group. Randomization to group was completed by the PI after inclusion criteria were met prior to consent. If the participant did not meet inclusion criteria, the reasons they did not meet criteria and the study aims were explained. They were thanked for their efforts and time. Included participants were block randomized in a 2 X 11 randomization schedule (see Figure 3.4).

Participants' Numbers	Experimental Group	Participants' Numbers	Attention-control Group
1	X	2	O
3	O	5	X
6 replaced by 16	X	7	O
8	X	9	O
10	O	17	X
13	X	11	O
15	O	18	X
19	O	20	X
22	X	21	O
12	X	23	O

Figure 3.4. Block Randomization

One participant dropped out during the initial period after screening but before starting interventions due to a fractured ankle. This participant's block randomization assignment was replaced with the next participant. This participant remained for the entire study.

Informed consent forms were specific to the group assignment (see Appendix J). Study protocol information was provided by the PI to patients. All risks, benefits, and possible alternative treatment modalities were explained to the candidates by the PI. At no time was coercion or intimidation used to persuade the candidates to enroll as study

participants. After consenting, each participant completed the Arthritis Impact Measurement 2 survey and Visual Analogue pain scale and was measured for range of motion by the PI. Blood for biomarkers was drawn by the PI and transported and stored at the University of Missouri-Kansas City (UMKC) biomedical laboratory previously described.

Single blinding. The study researchers, PI, and assistants were blinded until after participant assignment was complete. Research assistants and Professional Association of Therapeutic Horseman (PATH) riding instructors were not aware of participants assigned to the other group. Alias participant names were offered for confidentiality by the PI, but no participants requested alias names. To prevent bias, all measurement data collected after consenting was not viewed by the PI or RAs until completion of the interventions.

Institutional Review Board (IRB). Human and animal participant safety and confidentiality was a priority. The research protocol was approved by the UMKC Institutional Review Board (IRB) and given the protocol number 16-276. All participants signed an IRB-approved consent form particular to their assigned group (see Appendix J). At no time was coercion or intimidation used to persuade the candidates to enroll as study participants. All questions were answered with the exception of information related to their unassigned group's intervention.

The horses were not the subject of the intervention but were used to deliver the intervention. Fazio, Medica, Cravana, and Ferlazzo (2013) studied the effects of therapeutic riding on the horse and found that the horse's cortisol level did not increase with therapeutic riding for one hour. The UMKC Institutional Animal Use and Care Committee exempted this study from their approval.

Settings

Recruitment sites. Recruitment sites included four physicians' offices of the Kansas City Physician Partners that specialize in arthritis and are located in Midwestern metropolitan urban and suburban areas. The PI added another recruitment site, the Commemorative Air Force event located at the New Century Airport in Gardner, Kansas, which is an event that attracts older adults who potentially would have arthritis due to age, and who also would have the time available to join the study because many were retired. The participants were screened at a convenient place of their choosing which was either their work, home, or at Saint Luke's College of Health Sciences (where the PI works).

Intervention sites. Due West Therapeutic Riding Center, located in Kansas City, Kansas, was the site where the EAT intervention was delivered. This PATH-certified facility had an indoor arena of 200 X 100 feet and was equipped with all necessary safety equipment for serving riders with multiple disabilities. Horses and staff (experienced side-walkers and horse leaders) are trained for the ultimate safe administration of equine therapy. Several participants benefited from mounting ramps that facilitate riders getting on the horse. The facility is described in further detail in Appendix G. All experimental interventions were provided in the indoor arena on PATH-certified horses chosen for their quiet manner and matched by the PI to the riders' height and abduction at the hip joint. Cats, dogs, and goats, in addition to horses, also inhabit the riding center.

Arthritis education classes were provided in a conference room at Saint Luke's College of Health Sciences in Kansas City, Missouri. Measurements were performed in the College's simulation center by the PI. Blood was also collected at the college after initial screenings by the PI. Blood was analyzed by the PI at The University of Missouri-Kansas

City School of Nursing and Health Studies biomedical laboratory. In-depth descriptions of the facilities are listed in Appendix G).

Instruments

Instruments used in screening. An Opt-in form and the demographic screening tool were developed by the investigator (see Appendices H and I). The Opt-in form assessed interest in participating in the HEAT study. Demographic/screening information included: (a) race, (b) age, (c) history of osteoporosis (which excluded the candidate), (d) history of fear of, allergies to, or riding a horse within the last six months (all aspects that excluded participants), (e) availability of transportation to and from the study sites, (f) current medications, and (g) a self-reported diagnosis of arthritis type. Healthcare provider permission to participate in the study was documented on a prescription pad or by a signed letter from the office on official letterhead.

Feasibility. The first primary specific aim was to measure feasibility of the research protocol. Feasibility was defined as assessment of the recruitment and attrition process and protocols, the extent to which the intervention procedures could be implemented correctly, if fidelity could be maintained, how many participants were excluded, what measurements could be completed and within the timeframe allotted, compliance with the intervention, and missing data. These variables were measured by tracking participant recruitment and attrition, documentation of intervention attendance on an Excel spreadsheet, and tracking of fidelity on the EAT curriculum sheet and ExEd PowerPoint printouts. Of those recruited, the percentage of participants who met exclusion criteria and could not participate was determined on an Excel Spreadsheet with reasons noted for exclusion. Reasons were collated for reporting.

Planned procedures for conducting the HEAT study included obtaining the necessary settings, support facilities, and personnel. For the education control group, this meant obtaining a room with projection capabilities, time available for the room, and quality information to share each week for six weeks. The EAT intervention was dependent on securing the collaboration of a PATH-certified instructor, team of side-walkers and leaders, and a PATH-certified facility with ramps for easy mounting, quiet horses, and tack, such as light saddles and bridles. Also the facility had to provide equipment to perform activities listed in the protocol, such as a portable basketball hoop, cones, poles, and rings to place over the poles. The riding instructors were required to agree to the administration of the protocol as written. To maintain fidelity, it was required of the RA to be available each week at the same time, to be willing to complete CITI training and protocol training, and to agree to adhere to the protocol. Documentation of any issues with implementation was reported on the Protocol Impediment/Violation Form (see Appendix K).

Attrition was also tracked. An expected attrition rate of 20% or less was deemed appropriate after systematically reviewing similar studies (White-Lewis, Russell, Johnson, Cheng, & McClain, 2017). A high attrition rate would have indicated that the protocol was not feasible for participants to maintain participation for six weeks. This could be due to many reasons, including weather, time spent, soreness after riding, information not valued, or the travel was too extensive. Attrition was documented on an Excel spreadsheet by the PI.

The protocol designated approximate times for each step. Assessing if it was feasible to perform the protocol steps in the designated timeframes was measured by completion rates during given timeframes (one to one and a half hours to complete each

intervention). Compliance of the participants to each step of the intervention was tracked by the RA designated in the EAT group and the PI in the control group. Any variance was immediately corrected or documented and tracked for non-compliance. Documentation was on the same Excel spreadsheet as attendance and attrition.

Maintenance and security of data was assessed. Measuring any missing data evaluated the feasibility of gathering responses, blood, and documents at the different settings. Transport of the blood draws and their maintenance, refrigeration, and processing were documented to ascertain if any specimens were lost.

Acceptability. The second primary aim was to measure the acceptability of the study protocol. An exit survey (see Appendix L) was administered at week six with questions evaluating acceptability of various study aspects. The variables included measuring: (a) the EAT participants' intentions to continue or not with the therapeutic riding/exercise program after the study, (b) the participants' desire to move to the other treatment group, (c) the participants' knowledge of whether they were in the treatment or control group, (d) the participants' assessment of the adequacy of time per session, and (e) the participants' overall assessments whether the study was appropriate, or if measurements were too extensive. Desire to move from the control group to the treatment group or from the treatment group to the control group was measured for acceptability of their assignment. Knowledge of which group they were assigned to (treatment or control) was asked on the exit survey. Questions were also asked to determine whether the timing of each session (too long, too short, or just right) and the length of the overall study (too long, too short, or just right) were appropriate. The exit survey also included a yes/no question asking if the measures (surveys, blood draw,

and joint measurements) were too extensive. Suggestions for improving the study were measured with an open-ended question eliciting comments.

Range of motion. A table of each instrument's biopsychosocial related concept, variable, measurement tool/category, and reliability/validity statistics with empirical references is included in Appendix M). To assess range of motion, a hand-held goniometer that measures the angle of a joint by degrees was used by the PI. This has been used widely to measure joint performance for stiffness of backs, hips, knees, and shoulders. The participant bends the joint in different directions with the instructions to bend just until stiffness begins. Then the angle is measured and documented. Reliability for measuring muscle strength was good to excellent (Baker, Kin, Moreside, Wong, & Rutherford, 2016; Fieseler et al., 2015; Kolber & Hanney, 2012). Fieseler et al. (2015) reported an intra-class correlation (ICC) coefficient of 0.96-0.99 for shoulders using readings from a hand-held goniometer. Nussbaumer et al. (2010) reported an ICC 0.90 for hip abduction and deemed the goniometer reading valid compared to an electromagnetic tracking system. Findings were documented on the Range of Joint Motion Evaluation Chart, providing a visual depiction of the range of motion in joints and normal parameter ranges (see Appendix F). This valid and reliable tool was appropriate for transport between participants' homes, the riding facility, and the college, where measurements were obtained. The participants were measured at week zero, after the week three intervention, and at the end of the intervention period week six.

Pain. For evaluation of pain, The Visual Analog Scale (VAS) (see Appendix A) was utilized. It is a simple, quick, self-reporting mechanism to assess pain on a 1-100 mm scale and is commonly used to measure pain (Ferreira-Valente, Pais-Ribeiro, & Jensen, 2011).

Higher scores indicate a greater perceived pain. Successfully used in previous EAT research (Lechner et al., 2007), this tool has moderate to good reliability in measuring musculoskeletal pain with rho values of 0.60-0.77 (Boonstra, Schiphorst Preuper, Reneman, Posthumus, & Stewart, 2008). This tool was selected due to the convenience for participants of a paper document with moderate to good reliability. The participants were surveyed at week zero, after the week three intervention, and at the end of the intervention period week six.

Cartilage Oligomeric Matrix Protein and skeletal muscle troponin T Type 3 as biomarkers for EAT effects.

The serum levels of the Cartilage Oligomeric Matrix Protein (COMP) and skeletal muscle troponin T Type 3 (TNNT3) were measured to identify any effect of the interventions on two important aspects of arthritis: cartilage and muscle (Felson & Lohmander, 2009). COMP and TNNT3 were assessed for their potential use as biomarkers for EAT effects using enzyme-linked immunosorbent assays (ELISA), following the manufacturers' instructions and measuring differences in absorbance at 450 nm on a Power Wave Microplate Spectrophotometer (Bio-Tec instruments). All pipettes used for the ELISA assays had been calibrated within one year. The Power Wave Spectrophotometer does not require any external routine calibration in addition to self-test when powered on. These self-tests include checking the eight reading channels and one reference channel (photodiodes) to confirm they have adequate range in order to ensure that each channel can be normalized to the others and the light bulb to verify it is within operational limits. The ELISA assay for COMP (R&D Diagnostics) have a sensitivity of 0.036 ng/ml and Intra- and Extra-Assay precision lower than 5%. The ELISA assay for TNNT3 have sensitivity of 0.1

ng/ml and Intra- and Extra-Assay precision lower than 15%. When COMP was compared to radiographic findings in the knees of adults with osteoarthritis, serum COMP levels were elevated with progression of the disease ($p < 0.001$) (Hoch, Mattacola, McKeon, Howard, & Lattermann, 2011). A positive correlation was found by Skoumal, Kolarz, and Klingler, (2003) between increased serum levels of COMP and deterioration due to rheumatoid arthritis ($p < 0.007$).

There are three types of troponin: troponin I, troponin C, and troponin T. Each has a separate function. Troponin T is specifically found in skeletal and cardiac muscle (Mangla, 2015). In humans, three homologous genes evolved to encode three muscle type-specific isoforms: TNNT1 is for slow skeletal muscle, TNNT2 is for cardiac muscle and TNNT3 is for fast skeletal muscle (Wei & Jin, 2016). The subunit T is also required for calcium mediated activation of ATPase activity (HUGO Gene Nomenclature Committee, 2018). Abreu et al., (2014) previously studied serum troponin T, a sarcomeric protein that should not normally be found in serum, as a biomarker to measure skeletal muscle damage for community-dwelling older adults. Their intervention study of older adults, ages ranging from 64 to 94, consisted of two, 10-week strength training exercise programs to determine if serum troponin could be used as a biomarker for muscle. Thirty-four participants' serum was measured by troponin T ELISA assays. Serum troponin T levels decreased by 56% over the ten-week period. These authors hypothesized that if skeletal muscle's protection by layers of connective tissue is insulted, troponin T can leak into the vascular system and the blood, generating a protein that can be detected. Presence of this protein indicates pathology or increased muscle physiological turnover. The mean age of the participants in this study was 63 years old, with variations of exercise as the intervention. They found a statistically

significant difference in troponin levels after exercise in the older adult sample ($p=0.008$) between experimental and control groups (Abreu et al., 2014). The age and exercise were similar enough to the study protocol for EAT for older adults, that measuring serum troponin to indicate muscle health during this study was appropriate.

In this work serum troponin T from fast-twitch muscles was measured, which constitutes the majority of an individual's muscle mass (TNNT3). TNNT3 and COMP were measured prior to the study at zero weeks and after the study at six weeks. No measure was taken at three weeks for three reasons: (a) the needle stick to draw serum was kept at a minimum for acceptability, (b) muscle and cartilage changes would be more pronounced at six weeks, and (c) ELISA assays are costly.

COMP is used as a biomarker that monitors joint damage in patients with articular diseases (Pereira Nunes Pinto, Natour, de Moura Castro, Eloi, & Lombardi Junior, 2017). COMP is an extracellular matrix glycoprotein that is derived from cartilage, synovium, and menisci (Kluzek et al., 2015; Tseng et al., 2013). What COMP's role in joint health is not clearly understood (Kluzek et al., 2015). Protein levels of COMP in synovium are correlated with serum COMP levels (Kluzek et al., 2015), and they increase immediately after exercise such as moderate walking (Pereira Nunes Pinto et al., 2017). In patients with arthritis, COMP levels are elevated to the same degree as cartilage destruction (Vingsbo-Lundberg, Saxne, Olsson, & Holmdahl, 1998). The cartilage oligomeric matrix protein (COMP) is mainly expressed in cartilage, but also in tendon and ligament. Because it is a matrix protein, researchers have evaluated the presence of COMP in the serum (sCOMP) as a biomarker for joint damage, including damage caused not only by osteoarthritis (OA), but

also rheumatoid arthritis (RA) and knee trauma (Clark 1999; Niehoff, 2011). This makes COMP an appropriate measure for the HEAT study.

TNNT3 and COMP were measured prior to the study at zero weeks and after the study at six weeks. No measure was taken at week three for three reasons: (a) the needle stick to draw serum was kept at a minimum for acceptability; (b) muscle and cartilage changes would be more pronounced at six weeks; and (c) ELISA assays are costly.

Quality of life. The Arthritis Impact Measurement Scale 2 (AIMS-2) short form is a multidimensional disease specific scale that measured quality of life. Questions are answered and scored on a five-point Likert scale of: 1 – all days/always, 2 – most days/very often, 3 – some days/sometimes, 4 – few days/almost never, 5 – no days/never. Higher scores translate to more negative effects in the patient’s quality of life. It includes the following subscales: “mobility, physical activity (walking, bending, and lifting), dexterity, household activity (managing money and medications, housekeeping), social activities, and activities of daily living, pain, depression, and anxiety. AIMS-2 included the categories of arm function, social support, and work” (Carr, 2003, p. 114). The AIMS-2 has content, construct, and convergent validity when compared to the Sickness Impact Profile ($p < 0.001$) and the Medical Outcomes Short Form ($r > 0.60$) (Arkela-Kautiainen et al., 2003; Carr, 2003). Internal consistency is 0.79-0.89 with test-retest reliability of 0.72-0.97 (Arkela-Kautiainen et al., 2003). The HEAT study’s participants were surveyed at week zero, after interventions week three, and at the end of the intervention period week six.

Effect of the environment. This study measured the environment using a self-reported survey. The Environmental Attitudes Inventory Scale (see Appendix N), has been previously used to determine the influence of outdoors areas on stress relief (Beil & Hanes,

2013). The instrument has the following subscales: enjoyment of nature, support for interventionist conservation policies, environmental movement activism, conservation motivated by anthropocentric concern, confidence in science and technology, and environmental threat. Only the enjoyment of nature subscale was used in the HEAT study. Five questions are responded with a seven-level Likert score: 1 – strongly agree, 2 – agree, 3 – somewhat agree, 4 – undecided, 5 – somewhat disagree, 6 – disagree, 7 – strongly disagree. The tool’s test-retest reliability was 0.70 (Milfont & Duckitt, 2010). The participants were surveyed at week zero, after interventions week three, and at the end of the intervention period week six.

Procedure

Experimental intervention. The procedure for EAT was developed from previous literature (Aranda-Garcia et al., 2015; Frevel & Mäurer, 2014; Hammer et al., 2005; T. Homnick et al., 2015; H. S. Kim et al., 2014). A PATH-certified therapeutic riding instructor consulted on the EAT intervention curriculum. Procedural details steps are described in the Appendix O (Protocol Steps). Three cohorts of EAT participants rode for a six-week period with two to four participants in each cohort. The intervention was provided on the same day of the week for all cohorts. It was necessary to cohort the participants to accommodate the availability of the horses.

The experimental intervention, EAT, included grooming, stretching, and riding through a series of obstacles. Participant safety was of the highest priority during all interventions. The horses remained at a walk with two trained and experienced therapeutic riding side-walkers positioned on each side to support the rider on week one or longer if balance was deteriorated. Deterioration was determined by the side-walkers if the

participant was sliding or leaning to one side while riding. A Professional Association of Therapeutic Horsemanship (PATH) certified trainer and the PI were present at all times to ensure the safety of animal and rider.

Grooming included brushing the horse from head to tail, cleaning the feet, and then saddling and bridling the horse. This grooming activity creates stretching motions of the shoulders, raising the arms above the head, and bending the back to clean the horse's feet. Mounting was assisted by either steps or a ramp at the level of the horse's back. Some participants sat on the horse from the side while resting in a chair and then swung their legs over the back of the horse. All maneuvers were supported by two staff to ensure safety. After mounting, a series of riding tasks were performed for 30 minutes. Each week progressed to more difficult tasks from walking around the arena on horseback, stretching, and learning to communicate with the horse through the reins in week 1, to independent weaving through cones and leaning over the horse to complete tasks such as placing a ball in a basketball goal (see Appendix D). During riding, the participants were asked to drop their reins while the leader led the horse. Several stretching exercises such as knee lifts, ankle rolls, and hand to opposite knee touches were performed. Typically during riding, the rider adjusts to the varying movements of the horse which increases muscle, balance, and stretching (Yorke et al., 2008). Dismounting was physically supported for each participant by the PATH instructor for soft contact with the ground after sliding off the horse. Horses were then walked, unsaddled, and brushed by participants. Human-animal bonding time after riding was provided by allowing the participants time to groom the horses. Participants were provided with treats to give to the horses. Snacks were also provided by the PI for the humans, trainers, horse leaders, and side-walkers. Conversations about the EAT lesson

occurred. The side-walkers often commented how the horse positively reacted to the human rider. This was serendipitous and not a dictated part of the protocol.

Exercise attention control group. The exercise education attention control protocol curriculum was developed from traditional, evidence-based exercise education for adults and older adults with arthritis (Fernandes et al., 2013; Hughes, Wallace, & Baar, 2015), the exercise program from the Arthritis Foundation (“How-to Exercise With Arthritis,” n.d.), and previous literature (Bijlsma et al., 2011; Gecht-Silver, 2017; Kohn, Belza, Petrescu-Prahova, & Miyawaki, 2016; National Institute on Aging, 2011). The attention-control group attended an exercise education class for adults and older adults with arthritis (see Exercise Training for Adults with Arthritis in Appendix E). The attention control intervention included the same time requirements and similar travel requirements, and included similar group interactions as the experimental intervention (see Protocol Steps, Appendix O). The class curriculum was prepared by the PI, and the classes were reviewed with the RA for accurate delivery. Each cohort was able to choose the day and time to optimally meet their personal schedules. Once the day and time were selected, the classes were offered on the same day of the week, once a week for six weeks. Participants were asked to not increase their exercise until after the six-week study period. Education topics included: (a) an overview of arthritis and the benefits (social, physical, and psychological) of exercise, (b) stretching, endurance versus strength training, (c) pain limitations and tools to use in exercising, (d) intensity and planning, (e) starting and maintaining an exercise program, and (f) keeping exercise interesting and high intensity exercises when you have arthritis. All information was cited with links to the original sources. The curriculum encouraged discussion and sharing of experiences with arthritis. An exercise planning

calendar was developed during the classes with a personal plan to exercise after the study. PowerPoints were sent to each participant at the conclusion of the intervention period. Three cohorts of three to four participants attended the sessions.

Medications. Participants were instructed to continue all medications during the study. If medication for inflammation or arthritis pain/stiffness were prescribed, they were instructed to consult their physician and alter their medication schedule to allow peak performance during the EAT intervention. Changes of medications during the six-week period were allowed if deemed medically necessary by their healthcare provider.

Fidelity to Interventions

For consistency, the PI performed all measurements and was responsible for obtaining consent from all participants. Fidelity to the intervention was assessed by the RA with oversight by the PI by observing the EAT intervention for each step of the protocol using a protocol checklist. The RA was positioned in the center of the arena and corrected any deviation from protocol in real time. Any deviation was immediately communicated to the PATH riding instructor and documented on the participant's curriculum sheet, tracked, and reported.

For the attention control education group, the nurse RA delivered the education with the PI providing fidelity validation at each class. The PI attended all education classes and immediately corrected any protocol variances made by the RA during the sessions. The PI was present at all experimental and control interventions observing for correct implementation.

Research Assistant Training

The research assistant for the EAT group was an experienced horse trainer with an associate's degree in equine studies and 25 years experience in childhood and adult horse riding training of humans and horses. A master's-prepared advanced nurse practitioner who is an experienced faculty member at Saint Luke's College of Health Sciences was the RA who provided the exercise classes. The PI provided RA training to the study protocols – EAT protocol training to the EAT RA and arthritis education to the arthritis education RA. The PI completed the measurements, and the RA documented the results. Training on instruments administration documentation was completed by the PI with both RAs. The PI conducted RA training and demonstration with retraining as needed until satisfactory performance and adherence to the research protocols and documentation of instrument administration was observed by the PI.

Risk Prevention

As required by the Institutional Review Board, all precautions were taken to ensure the safety and protection of all study participants. There is a paucity of information about equine-assisted therapy safety and risks. Much of the information comes from an athletic or leisure study and not therapy sessions with the protective mechanisms such as leaders and side-walkers and certified PATH instructors (Ball et al., 2013). Cook (2013) surveyed 114 hippotherapy sites with those protections in place in 2011 and 123 in 2013. The results reported an injury rate of one per 4,850 hours of riding. Of these injuries 9 out of 10 were injuries to the staff and not the clients. The one client injury occurred when a horse stepped on the client's foot. No injury resulted in permanent or disabling damage.

The precautions implemented for the participants' safety are described next. A physician's/APRN's release for participation in the study was obtained by the PI for all EAT participants. Safety measures included consultation from a Professional Associations Certified Instructor (PATH) about the study. The study was conducted at a PATH-certified facility, and all procedures were monitored by a PATH-certified instructor. Antimicrobial soap was used prior to and after interacting with the horse. The PATH-certified horses were selected for their calm and accepting demeanor. Horses were matched to riders based on the abduction score measured during screening. A veterinarian selected by the PATH instructor verified the health of the horses and their vaccination status prior to the study. To maintain balance of the participants, an appropriate mounting apparatus was used, and trained assistants walked by the side of the participant. A horse leader directed the horse if the participants were instructed to drop their reins for stretching or if the participant could not safely navigate the obstacles. These leaders walked with the horses the entire lesson to be prepared to help if needed. Participants wore helmets at all times within three feet of the horse, and thick reins were offered for any participant with arthritic hands. All participants declined this offer. Additionally, a safety training session based on the *Pony Club Safety Booklet – 2017* (USPC Safety Committee, 2017) was administered to each experimental group participant with a demonstration/return demonstration evaluation of safety measures by the PATH instructor or the PI (see Safety Training for Participants in Appendix P). The participants were monitored for adherence to the safety instructions for any discomfort during the intervention by the PI and the PATH instructor. If at any time the participant described a desire not to perform the protocol task, they were not required to complete it.

Each participant was offered the opportunity to continue with the therapeutic riding at their own cost after the intervention to prevent human-animal bond separation anxiety.

Laboratory Procedures

Laboratory work included training and supervision of the PI by Dr. E. Abreu, who has been performing ELISA assays procedures for more than 15 years. His current research included the use of ELISA for the evaluation of serum levels of multiple biomarkers; (COMP, fast and slow troponin T, Sclerostin, Hyaluronan, and Tenomodulin) in older adults before and after an eight-week exercise program especially designed for older adults (Stay Strong Stay Healthy) that included resistance exercise. Dr. Abreu supervised the administrations of procedures, analysis, and interpretation of the data. ELISA assays are designed to detect and quantify these specific proteins and antibodies. This technology immobilizes an antigen that is mixed with an antigen linked to an enzyme. Proteolytic cleavage of the cartilage causes fragments that can be detected in serum and can be measured as response to treatment (Neidhart et al., 1997; Posey & Hecht, 2008). Within one hour of blood draw, the sample was transported by the PI to UMKC's lab and spun in a Hettich centrifuge ROTOFIX 32A (Hettich Instruments) at 1,000x g for 15 minutes to separate the serum. The serum was retrieved, labeled, and then frozen in a -80 degree freezer. After all specimens were obtained, they were thawed and aliquoted for future use if necessary. COMP and TNNT3 ELISA assays were processed per manufacturer's instructions. Repeated rinses with de-ionized water, conjugate administration, and dilutions were all performed per instructions. Detection of the enzyme activity was measured after incubation of the antigen-antibody interaction with administration of a substrate. Once incubated, the optical density was calculated in each sample and then quantified (Protein

Biology Resource Library, n.d.). Readings were then compared to standards processed in the same assay. Dr. Abreu was present during all ELISA procedures and corrected any deviations to prevent problems and ensure that the protocols were followed.

Data Management

The data were collected and recorded on paper at the various settings. The participants were de-identified at screening and these data were kept secure by the PI until all data were collected. After the completion of the interventions and the ELISA assays were finished, the data were entered by the PI into the REDCap Data Management system (REDCap, n.d.). Data analysis was conducted using SPSS version 22 (IBM Knowledge Center, n.d.) and supervised by Dr. A. Cheng, the University of Missouri-Kansas City biostatistician. After data collection and verification by the PI, the data were entered into SPSS and cleaned, statistical tests were performed, and methods/results were checked by Dr. Cheng (see Data Analysis in Appendix Q). Data were considered non-parametric due to the small sample size. For demographic data, percentages and themes were reported. Feasibility and acceptability results were reported with percentages, and all comments were listed for the responses to the open-ended question. The exploratory variables were calculated for between groups with Friedman's test. For between groups Mann Whitney U calculated the results. Significance was set at $< .05$ for all tests. For serum COMP and TNNT3 serum troponin, the percent change from week zero to week six was calculated using Excel software. The percent change was then calculated by Mann Whitney U to determine significance between the groups.

The QOL and ROM values were subdivided into meaningful categories. For the QOL variable, the scored values were recoded to produce meaningful results. Negative

questions were changed to positive values. The original creator of the AIMS-2 measurement tool completed a factor analysis, and these factors were used to create meaningful categories of upper limb, lower limb, symptoms, and social interaction (Guillemin et al., 1997). For the ROM variable, the categories chosen were physiological body parts of back, knee, hips, and shoulder. In both cases the scores were combined into a summative score, and calculations were completed using the summative score.

CHAPTER 4

RESULTS

Chapter 4 is a report of findings related to the primary and secondary research questions. This chapter is organized by primary research questions followed by exploratory research questions.

Primary Research Questions

Research Question 1

What is the feasibility of adults and older adults with arthritis attending a six-week equine-assisted therapy program compared to an exercise education attention control group?

This section is organized by:

- Enrollment, allocation, follow up and analysis
- Intervention dose and timing
- Attrition
- Results for each research question

Enrollment, allocation, follow-up, and analysis. Figure 4.1 depicts numbers for enrollment, allocation, follow-up, and analysis. Recruitment was successful in attracting 51 individuals who were assessed for eligibility after completing the Opt-In form. Thirty were excluded, which left 21 who were randomized into the EAT (n=11) or ExEd group (n=10). Of the 11 who were allocated to the EAT group, one dropped after the first week's session due to hip pain, and the remaining 10 received the intervention. No participants were lost to follow-up in either group. Recruitment was expanded from physicians' offices to include a Commemorative Air Force event in Gardner, Kansas, due to falling behind the recruitment timeline by three months during the recruitment phase.

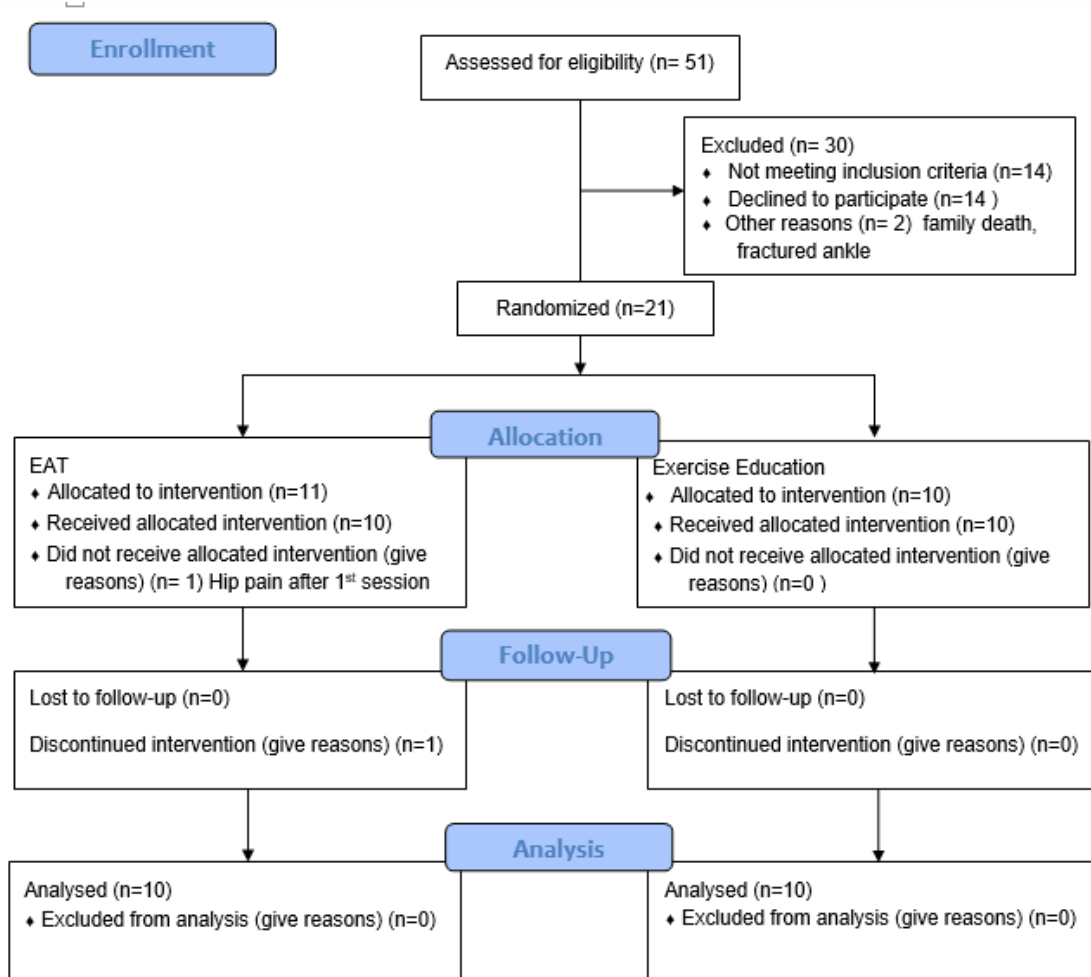


Figure 4.1. Study Enrollment, Allocation, Follow-up, and Analysis Using CONSORT Guidelines (Moher et al., 2010).

Table 4.1 delineates the demographics of the sample completing the study. The mean age of the EAT group was 61.90 with a range from 53 to 70. The mean age for the ExEd group was 65.80 with a range of 54 to 75. The majority of participants were Caucasian (n=15/75%); other participants comprised African Americans (n=3/15%), Asian (n=1/5%), and Hispanic (n=1/5%). A variety of arthritis diagnoses were self-reported by participants, with osteoarthritis reported most often (n=8/40%), rheumatoid (n=4/20%), non-specific arthritis (n=4/20%), polyarthropathy-autoimmune, and erosive arthritis (n=1/5%).

Age was not statistically significant ($p=.358$) between the EAT and the ExEd groups, but gender and race were statistically significantly different ($p=$, $p=.000$). Arthritis diagnosis was not significantly different between the groups ($p=.060$)

Table 4.1

Sample Demographics (n=20)

		Both Groups	EAT	ExEd	<i>p</i> value between groups
Age	Range	53-75	53-70	54-75	
	Mean	63.85	61.90	65.80	$p=.358$
Gender	Males (n/%)	4/20	4/40	0	
	Females (n/%)	16/80	6/60	10/100	$p=.037$
Race	African American (n/%)	3/15	1/10	2/20	
	Asian (n/%)	1/5	1/10	0	
	Hispanic (n/%)	1/5	1/10	0	
	White (n/%)	15/75	7/70	8/80	$p=.000$
Arthritis Diagnosis	Arthritis – nonspecific (n/%)	4/20	2/20	2/20	
	Osteoarthritis (n/%)	8/40	7/10	1/10	
	Rheumatoid Arthritis (n/%)	4/20	0	3/30	
	Osteo and rheumatoid arthritis (n/%)	2/10	0	2/20	
	Polyarthropathy (n/%)	1/5	0	1/10	
	Erosive Arthritis (n/%)	1/5		1/10	$p=.060$

Note. T test calculated age and gender. Chi square calculated race and diagnosis. *P* value <.05

Intervention dose. The intervention protocol was performed as prescribed in both the control (100%) and intervention groups. Minor infractions of the protocol included: (a) one participant trotted on three separate occasions for less than 4 strides (n=3); (b) one participant remained in two-point for ¼ of the arena more than protocol dictated (n=1), and (c) one participant had their joint measured before week four rather than after week three (n=1). All measures were completed within the designated time except for the one

participant who was measured prior to week four rather than after week three. This participant was too stiff to lie on the floor to be measured. At week four a table was available for this participant to lie on and be measured. Participants complied with the interventions with the only exceptions occurring with trotting and two-point mentioned above.

A visual depiction of the dose and sequencing of EAT and ExEd sessions is in Table 4.2. The intervention had six components that included intervention delivered weeks one-six. The intervention “dose” consisted of “intended” and “delivered” dose. The “intended” dose was the number of participants who were intended to receive the intervention. The “delivered” dose was the number who actually received the intervention/the “intended” dose numbers. The “delivered dose timing” was characterized by the number of participants whose intervention was delivered once a week for six weeks. Alterations in timing include reasons the timing was changed.

Table 4.2

Intervention Dose and Sequencing

Participant	Lesson Number
EAT	
1	1 2 3 4 5 6
5	1 2 3 4 5 6
6	1 - - - - -
8	1 2 3 4 5 6
13	1 2 3 4 5 6
16	2 3 4 5 6 1
17	1 2 3 4 5 6
18	1 2 3 4 5 6
20	1 2 V 4 5 6 H 3
22	1 2 3 4 5 6
14	1 2 3 H 4 5 6
ExEd	
2	1 2 3 4 I 5 & 6
3	1 2 3 4 5 6
7	1 2 3 I 4 6 & 5
9	1 2 3 4 5 6
10	1 2 3 4 5 6
11	1 2 3 4 5 6
15	1 2 3 4 5 H 6
19	1 2 3 4 5 H 6
21	1 2 3 4 5 H 6
23	1 2 3 4 5 H 6

Note. V = Vacation H = Thanksgiving Holiday I= Illness

Table 4.3

EAT Dose and Timing Adherence to Protocol

EAT	Intended Dose	Delivered Dose	Delivered Dose Timing	Alterations in Timing
Week 1	11	11/11 (100%)	11/11 (100%)	
Week 2	10	10/10 (100%)	9/10 (90%)	1 participant dropped after week 2
Week 3	10	10/10 (100%)	8/10 (80%)	The replacement participant started week 2 but finished 6 doses. Also 1 participant was on vacation but added a lesson at the end
Week 4	10	10/10 (100%)	8/10(80%)	Thanksgiving holiday – the therapeutic center was closed for 2 participants week 4
Week 5	10	10/10 (100%)	9/10(90%)	Replacement participant was off 1 week
Week 6	10	10/10 (100%)	9/10(90%)	Replacement participant was off 1 week

Table 4.4

ExEd Dose and Timing Adherence to Protocol

Exercise Education	Intended Dose	Delivered Dose	Delivered Dose Timing	Alterations in Timing
Week 1	10/10 (100%)	10/10 (100%)	10/10 (100%)	
Week 2	10/10 (100%)	10/10 (100%)	10/10 (100%)	
Week 3	10/10 (100%)	10/10 (100%)	10/10 (100%)	
Week 4	10/10 (100%)	10/10 (100%)	9/10(90%)	1 participant was ill but came early the next week for a replacement lesson
Week 5	10/10 (100%)	10/10 (100%)	9/10(90%)	1 participant was ill but came early the next week for a replacement lesson
Week 6	10/10 (100%)	10/10 (100%)	6/10(60%)	Did not have class on the day after Thanksgiving

All participants received the six intended doses. Timing was interrupted with illnesses, holidays, and the replacement of one participant due to attrition. The participants were willing in all but one situation to make up the time that they missed for illness, vacations, and holidays. For the EAT group, the lesson they missed was delivered at the end of their cohort session for illness or when the one participant replaced the person who dropped the study. He came one week at the end of the EAT intervention to make a total of six doses. The ExEd group has several participant illnesses with one participant hospitalized for a week. The attendance of the education control group was 83%. Three sessions were unattended due to illness. All returned to the study after their illness, and two requested the lesson missed to be delivered prior to the next lesson. This was granted. In the United

States, Thanksgiving is a national holiday. The cohorts that were scheduled on Thanksgiving Friday (both EAT and ExEd) were not required to attend. Absences due to the heat and cold, which fluctuated from 92 degrees Fahrenheit at the hottest to 23 degrees at the coldest, did not occur. All EAT interventions were in an indoor arena, which mitigated the effects of the temperatures. Cool washcloths and bottled water were available for the hot months and hot chocolate for the cold months. Despite the extremes in weather, no participants opted to miss any intervention sessions. All lessons (100%) were resumed after the holiday week in the order intended. One participant travel to Germany for vacation during the holiday but came for her make-up lesson after the holiday.

Attrition. Attrition was anticipated to be 20%. All participants except one who started the intervention finished, which resulted in an attrition rate of 0.5%. After the first week, one participant of the EAT group felt soreness in her hips and contacted her physician, who stated that she should discontinue the study. She was contacted several times for two months after the intervention and with rest, returned to pre-study functionality, stiffness, and pain. Attendance for the EAT group was 100%, although one participant missed a class due to a prescheduled vacation. She then added a session at the end for a normal dose of six weeks of intervention. The replacement participant for the person who had hip pain, started on week two and continued for the required dose of six.

Feasibility. The feasibility research question results c, d, g, h, i and j are displayed in Table 4.5.

Table 4.5

Research Question 1 - Feasibility

Question Number	Research Question		Result
RQ1c	To what extent can we maintain adequate fidelity with the intervention?	EAT curriculum delivered correctly	100%
		Education curriculum delivered correctly	100%
RQ1d	Does the recruitment procedure sequence produce study participants?	Target participant sample	Met
RQ1g	To what extent are the measurements completed?	AIMS-2sf	100%
		VAS	100%
		Environmental Inventory Scale	100%
		Joint Measurements	100%
		Blood draws	100%
RQ 1h	Were the measurements able to be performed within the designated time?	Education group	100%
		EAT sessions (1 part was measured before week 4 rather than after week 3)	99%
RQ 1i	Do the participants comply with the intervention?	Noncompliance	
		Trotting (same participant) two-point for more time than allotted	3 times 2 times
		Required modified two-point position (same participant)	3 times
RQ 1j	How much data is missing?		0%

Research Question 2

For adults and older adults with arthritis, what is the acceptability of the study protocol with equine-assisted therapy as the intervention?

Implementation, blinding, and duration. The following is a discussion of research question 2 assessing the acceptability of the study protocol. Table 4.6 is a visual display of all sub-questions and their collated responses. Twenty percent or 2/10 of the EAT group intended to continue with EAT after the study. Ten or 100% of the exercise education

control group intended to implement the exercise plan after study completion. The groups were unaware of the opposite study group's assignment, and therefore 100% did not ask to change groups. Sixteen of twenty or 80% were aware that their group assignment was either the experimental or control group with 4/20% unaware. All participants (100%) felt the sessions' length (dosage) was appropriate. Two participants in the EAT group or ten percent of the total group expressed a desire for a longer study (duration) with 18/90% out of both EAT and ExEd groups responding that the length of the study was just right. Several participants commented to the PI and RA after both groups' sessions were completed that they were sad to end the group activities.

When asked if the measurements were too extensive, 20/20 or 100% said no. The open-ended question resulted in positive comments with one suggestion to take a two-week break and then continue with another six-week intervention.

Timeframe and seasonal effects. This randomized controlled pilot study was completed in the Midwestern United States in a five-month timeframe and spanned the very hot summer season through fall to extreme cold in December. Temperature modulating techniques such as cool washcloths on participants' necks during the warm months and hot chocolate in the very cold winter months were offered. Despite temperatures in the 90s and down to the 40s, the participants' attendance did not vary due to the weather.

Table 4.6

Research Question 2 - Acceptability

Question Number	Research Question		Result
RQ2a	Do the study participants intend to continue the intervention after the end of the study?	EAT	
		Yes	2/20%
		No	8/80%
		Exercise implementation	
		Yes	10/100%
		No	0/0%
RQ2b	Do the participants stay in the assigned groups, e.g. not wanting to move from control group to treatment group?	The groups were unaware of the other group	0%
RQ2c	Do participants know that they are in the treatment group or control group at the end of the study?	Yes	16/80%
		No	4/20%
RQ 2d	Do the participants feel the time spent per session is too long, too short, or just right?	Too long	0
		Too short	0
		Just right	100%
RQ2e	Do the participants feel the time spent in the study (6 weeks) was too long, too short or just right?	Too long	0
		Too short	2/10%
		Just right	18/90%
RQ2f	Do the participants feel the measurements were too extensive?	Yes	0
		No	20/100%
RQ2g	Any other comments about the study?	No Other Comments: Yes warmer weather, more hugs, champagne Had a good time Longer duration - Have participants take a 2-month break and then resume riding for six weeks I had a wonderful experience and love every minute. The benefits were/are extraordinary	4

Exploratory Research Questions

Exploratory Research Question 1

What is the effect of an equine-assisted therapy intervention compared to an exercise attention-control intervention on pain in adults and older adults with arthritis? Pain was measured in millimeters by the PI and documented after all interventions were completed. Back, knee, hip, and shoulder pain results are reported in the following individual sections and collated in Table 4.7. Baseline pain readings on a 100mm scale for the intervention group was back 41, knee 46, hip 44, and shoulder 49. For the control group pain, at baseline was: back at 39, knee 44, hip 34, and shoulder 18.

Back pain. Between group differences: The results indicated no significant differences between the groups at week 0 ($p=.307$) and week 3 ($p=.174$). There was a significant difference between groups at week 6 ($p=.021$).

Within group differences: Within the EAT group the pain scores significantly decreased over time (41.10 and 28.70, 14.80, $p=.006$). Within the ExEd group the pain did not decrease significantly over time (39.00, 33.70, and 29.60, $p=1.00$).

Knee pain. Between group differences: The study participants' results showed no significant differences between the groups at week 0 ($p=.762$), week 3 ($p=.326$) or week 6 ($p=.272$).

Within group differences: Within the EAT group the pain scores did not significantly decrease over time (46.10 and 27.50, 24.40, $p=.061$). Within the ExEd group the pain did not decrease significantly over time (43.90, 38.60, and 37.60, $p=.926$).

Though the experimental group and control group did not have statistically significant differences in knee pain, the EAT group's knee pain was trending downward ($p = 0.061$).

Hip pain. Between group differences: The participants' results indicated no significant differences in hip pain between the groups at week 0 ($p = .596$), week 3 ($p = .970$) or week 6 ($p = .225$).

Within group differences: Within the EAT group the hip pain scores did significantly decrease over time (43.90 and 31.00, 24.80, $p = .027$). Within the ExEd group the hip pain remained relatively the same between weeks 0 and 3 and increased slightly at week 6 (34.30, 34.80, and 24.80, $p = .122$).

Shoulder pain. Between group differences: Shoulder pain at week 0 was not significant ($p = .162$) or at week 3 ($p = .307$) and not significant at week 6 ($p = .448$).

Within group differences: Within the EAT group the shoulder pain scores did significantly decrease over time (48.90 and 26.80, 16.10, $p = .007$). Within the ExEd group the shoulder pain increased at week 3, then decreased at week 6, but not to the baseline value (17.80, 34.60, and 20.00, $p = .527$). Shoulder pain among the EAT group was decreased the most out of the four pain dependent variables.

Exploratory Research Question 2

What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on range of motion in adults and older adults with arthritis?

Back ROM. An increase of the back ROM indicates a more mobile and healthier back.

Between group differences: Between groups back ROM at week 0 was not significant ($p=.59$) or at week 3 ($p=.344$) but was significant at week 6 ($p=.002$).

Within group differences: Within the EAT group the ROM scores significantly increased over time (356.30 and 415.60, 445.10, $p=.008$). Within the ExEd group their ROM did not increase significantly (327.80, 379.10, and 368.70, $p=.670$

Knee ROM. With knee ROM, a lower number or less degrees of angle indicates healthier knee function

Between group differences: Knee ROM between groups at week 0 was not significant ($p=.427$) or at week 3 ($p=.104$) and not significant at week 6 ($p=.198$).

Within group differences: The EAT group ROM scores did not significantly decrease over time (155.40, 225.70, and 116.60, $p=.122$). The ExEd group ROM did decrease significantly (171.30, 163.40, and 128.40, $p=.021$).

Hip ROM. Healthy hip ROM are indicated by higher angular degrees.

Between group differences: Hip ROM between groups at week 0 was not significant ($p=.496$) or at week 3 ($p=.364$) and but was significant at week 6 ($p=.008$).

Within group differences: The EAT group ROM scores did significantly increase over time (356.30, 415.60, and 445.10, $p=.008$). The ExEd group was not significant and increased slightly between weeks 0 and 3 then decreased slightly at week 6 (327.80, 379.10, and 368.70, $p=.670$).

Shoulder ROM. Healthy shoulder ROM are indicated by higher angular degrees.

Between group differences: Between groups at week 0 was not significant ($p=.449$). Shoulder range of motion was significant between groups at week 3 ($p=.008$) and not at week 6 ($p=.54$).

Within group differences: The EAT group's scores increased but not significantly over time (542.60, 611.70, and 620.60, $p = .202$). The ExEd group shoulder ROM increased at week 3 then decreased at week 6 to the baseline value (489.20, 503.70, and 486.60, $p = .741$).

Exploratory Research Question 3

What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on quality of life in adults and older adults with arthritis?

The AIMS-2 is designed with the high scores indicating illness and low scores indicating a higher quality of life (Meenan et al., 1992).

Upper limbs QOL. Between group differences: Upper limb QOL was not significant between groups at week 0 ($p = .848$) but was significant at both week 3 ($p = .008$) and at week 6 ($p = .008$).

Within group differences: The EAT group scores did decrease significantly from week 0 to week 3 and then remained the same at week 6 (9.70, 8.20, and 8.20, $p = .002$). The ExEd group remained the same through all weeks (10.10, 10.80, and 10.80, $p = .202$).

Lower limbs QOL. Between group differences: Between groups at week 0 was not significant ($p = .908$), week 3 ($p = .1.00$) and at week 6 ($p = .238$).

Within group differences: The EAT group scores did decrease significantly. The mean scores decreased from week 0 to week 3 and then further at week 6 (13.40, 12.40, and 10.50, $p = .021$). The ExEd group lower limb QOL decreased but not significantly (13.50, 12.80, and 12.50, $p = .449$).

Affect QOL. Between group differences: Between groups at week 0 was not significant ($p=.322$) or at week 3 ($p=.470$) and but was significant at week 6 ($p=.043$).

Within group differences: The EAT group affect scores did significantly decrease over time (9.40, 8.80, and 6.40, $p =.030$). The ExEd group's affect scores decreased slightly but not significantly from baseline to week 6 (10.40, 9.70, and 9.20, $p=.303$).

Symptoms QOL. Symptoms were defined by Guillemin et al. (1997) as arthritis pain. Between group differences: Between groups at week 0 was not significant ($p=.590$) or at week 3 ($p=.148$) and was not significant at week 6 ($p=.170$).

Within group differences: The EAT group's symptom scores did not significantly decrease over time but were trending downward to significance (9.30, 7.00, and 6.60, $p =.052$). In the ExEd group the symptom scores decreased slightly but not significantly from baseline to week 6 (5.60, 9.10, and 8.30, $p=.336$).

Social interaction. Between group differences: Between groups at week 0 was not significant ($p=.848$) or at week 3 ($p=.562$) and was not significant at week 6 ($p=.067$).

Within group differences: The EAT group's social interaction scores did not significantly decrease over time (10.80, 10.20, and 9.30, $p =.164$). The ExEd group's scores increased slightly but not significantly from week 3 to week 6 (10.70, 10.70, and 9.30, $p=.164$).

Exploratory Research Question 4

What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on enjoyment of nature in adults and older adults with arthritis? With enjoyment of nature, a lower score represents a higher level of enjoyment of nature.

Between group differences: Between groups at week 0 was not significant ($p=.848$), at week 3 ($p=.562$) and was not significant at week 6 ($p=.067$).

Within group differences: The EAT group enjoyment of nature did not significantly decrease over time (11.00, 11.60, and 10.70, $p=.164$). The ExEd group also did not significantly decrease over time (14.80, 14.00, and 15.40, $p=.597$).

Exploratory Research Question 5

What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on Cartilage Oligomeric Matrix Protein biomarker for cartilage in adults and older adults with arthritis? The biomarker COMP was measured at baseline and after interventions were completed. Percent change from baseline to post intervention were calculated with no significant treatment effect from pre to post intervention (41.98, $p=.496$).

Exploratory Research Question 6

What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on serum troponin measuring muscle in adults and older adults with arthritis? Serum troponin was measured at baseline and after interventions were completed. Percent change from baseline to post intervention were calculated with no significant treatment effect from pre to post intervention (185.03, $p=.821$).

Table 4.7 lists the dependent variables, tools that measured the dependent variables, and the results. The results are displayed horizontally within groups and vertically between groups. Statistical significance is set at $p<0.05$. Statistically significant values are signified with an asterisk.

Table 4.7

Results

Results DV/Tool			Baseline Week 0		Mid-intervention Week 3		Post-intervention Week 6		Within Group
		Group	Mean	SD	Mean	SD	Mean	SD	
94	Pain (mm) VAS	Back	EAT	41.10 ± 30.60		28.70 ± 28.88		14.80 ± 18.47	$p = .006^*$
			ExEd	39.00 ± 28.63		33.70 ± 24.38		29.60 ± 20.93	$p = 1.00$
		Between Groups	$p = .307$		$p = .174$		$p = .021^*$		
		Knee	EAT	46.10 ± 30.59		27.50 ± 24.55		24.40 ± 26.51	$p = .061$
			ExEd	43.90 ± 25.74		38.60 ± 23.48		37.60 ± 27.30	$p = .926$
		Between Groups	$p = .762$		$p = .326$		$p = .272$		
		Hip	EAT	43.90 ± 37.07		31.00 ± 31.06		24.80 ± 19.70	$p = .027^*$
			ExEd	34.30 ± 26.31		34.80 ± 21.00		24.80 ± 19.70	$p = .122$
		Between Groups	$p = .596$		$p = .970$		$p = .225$		
		Shoulder	EAT	48.90 ± 38.07		26.80 ± 25.50		16.10 ± 21.47	$p = .007^*$
			ExEd	17.80 ± 11.35		34.60 ± 28.42		20.00 ± 22.49	$p = .527$
		Between Groups	$p = .162$		$p = .307$		$p = .448$		
	ROM (degrees) Goniometer	Back	EAT	356.30 ± 93.10		415.60 ± 82.74		445.10 ± 85.99	$p = .008^*$
			ExEd	327.80 ± 112.40		379.10 ± 141.51		368.70 ± 73.30	$p = .670$

Results DV/Tool		Baseline Week 0		Mid-intervention Week 3		Post-intervention Week 6		Within Group
		Group	Mean	SD	Mean	SD	Mean	SD
		Between Groups	$p = .59$		$p = .344$		$p = .002^*$	
	Knee	EAT	155.40 ± 56.38		225.70 ± 317.45		116.60 ± 23.40	$p = .122$
		ExEd	171.30 ± 42.35		163.40 ± 44.40		128.40 ± 39.44	$p = .021^*$
ROM (degrees) Goniometer	Knee	Between Groups	$p = .427$		$p = .104$		$p = .198$	
	Hip	EAT	356.30 ± 93.02		415.60 ± 82.74		445.10 ± 85.99	$p = .008^*$
		ExEd	327.80 ± 112.40		379.10 ± 141.51		368.70 ± 73.30	$p = .670$
	Shoulder	Between Groups	$p = .496$		$p = .364$		$p = .021^*$	
		EAT	542.60 ± 117.38		611.70 ± 49.69		620.60 ± 44.47	$p = .202$
		ExEd	489.20 ± 101.94		503.70 ± 44.21		486.60 ± 61.02	$p = .741$
	Upper Limb	Between Groups	$p = .449$		$p = .008^*$		$p = .54$	
		EAT	9.70 ± 2.87		8.20 ± 1.81		8.20 ± 1.81	$p = .002^*$
		ExEd	10.10 ± 1.88		10.80 ± 3.16		10.80 ± 3.16	$p = .202$
	Lower Limb	Between Groups	$p = .848$		$p = .008^*$		$p = .008^*$	
		EAT	13.40 ± 3.78		12.40 ± 3.81		10.50 ± 2.99	$p = .021^*$
		ExEd	13.50 ± 4.30		12.80 ± 4.08		12.50 ± 4.035	$p = .449$
	Affect	Between Groups	$p = .908$		$p = 1.00$		$p = .238$	
		EAT	9.40 ± 4.43		8.80 ± 3.52		6.40 ± 2.55	$p = .030^*$
		ExEd	10.40 ± 3.27		9.70 ± 3.23		9.20 ± 2.94	$p = .303$

Results DV/Tool		Baseline Week 0		Mid-intervention Week 3		Post-intervention Week 6		Within Group	
		Group	Mean	SD	Mean	SD	Mean	SD	
96	QOL (Likert) AIMS-2	Symptoms	Between Groups	$p = .322$		$p = .470$		$p = .043^*$	
			EAT	9.30 ± 3.50		7.00 ± 3.56		6.60 ± 3.41	$p = .052$
			ExEd	8.60 ± 2.12		9.10 ± 1.66		8.30 ± 2.54	$p = .336$
		Social Interaction	Between Groups	$p = .590$		$p = .148$		$p = .170$	
			EAT	10.80 ± 3.23		10.20 ± 2.61		9.30 ± 3.00	$p = .164$
			ExEd	10.70 ± 2.36		10.70 ± 2.59		11.70 ± 2.869	$p = .303$
	Environment (Likert)	Between Groups	$p = .848$		$p = .562$		$p = .067$		
		EAT	11.00 ± 5.25		11.60 ± 4.33		10.70 ± 4.35	$p = .479$	
		ExEd	14.80 ± 8.09		14.00 ± 8.26		15.40 ± 7.50	$p = .597$	
	Comp (% chg) Troponin (% chg)	Between Groups	$p = .323$		$p = .621$		$p = .184$		
			41.98 ± 63.37					$p = .496$	
			185.03 ± 663.33					$p = .821$	

Note. Friedman's test calculated within group statistics. Mann Whitney U calculated between group statistics. Mann Whitney U calculated Comp and troponin. Significance was set at 0.05.

CHAPTER 5

DISCUSSION

Chapter 5 includes a discussion of feasibility, acceptability, and exploratory results of the HEAT randomized controlled trial within the context of current literature. The following is a summary discussion of research requirements, including staff, horses, facilities, and support for the HEAT study. Study feasibility, acceptability, recruitment, screening implementation, intervention implementation, and attrition, interpretation of exploratory results, limitations, and conclusions follow.

Study Feasibility

The results of this study offer some support for the feasibility of conducting EAT intervention research. This research requires securing many facilities and adequate support staff.

Securing Facilities and Support Staff

Sites for the HEAT study were acquired prior to recruiting the participants. The use of a PATH-certified therapeutic riding center, PATH-certified riding instructors and horses, riding assistant staff, research assistants for both the experiment intervention and the control intervention, recruitment sites, and the use of a biomedical laboratory were necessary support components that needed to be acquired. The use of a therapeutic riding center, its equipment, and staff was an essential safety element to be able to conduct this research. The owner of the PATH facility, Ms. Sharp, held a Master's degree in Special Education with an emphasis on behavior disorders, emotional disturbances, and autism. She supported our scientific research with input and review of the EAT protocols and the EAT curriculum.

Ms. Sharp provided the horses, facility, volunteers, and equipment. The facility staff included a volunteer coordinator who obtained 32 volunteer side-walkers and horse leaders. The number of volunteers required could not be determined in the planning phase since the need for side-walkers was dependent on the participants' riding experience and balance. Additional study staff required were two research assistants, one with experience in equine training of humans and horses, and the other an advanced nurse practitioner faculty to deliver the ExEd intervention.

A PATH-certified setting ensured a high quality experience compared to settings reported in most EAT literature. In a systematic review of 31 EAT intervention studies, comparatively, the facilities used were a single riding center/school/hall (n=11/31, 35%), riding setting not reported (n=8/31, 26%), therapeutic riding center not PATH-certified or not reported (n=7/31, 23%), PATH-certified centers (n=3/31, 10%), multiple therapeutic centers (n=1/31, 3%), and a rehabilitation center specializing in EAT (1/31, 3%) (White-Lewis et al., 2017). Obtaining these high quality facilities and staff supports the feasibility of performing this type of research.

Recruitment

Previous EAT intervention studies recruited older adults from neighborhoods where older adults lived, via a mailing to older adults, from town meetings where older adults participated, and from hospitals where older adults were treated for disease-specific issues (Aranda-Garcia et al., 2015; Araujo et al., 2011; Beinotti et al., 2013). With the HEAT study, a target sample of older adults and adults with arthritis was required. A physician's health system with four offices specializing in different forms of arthritis was chosen for recruitment. Mailings were considered invasive by the physicians and burdensome for the

office staff to handle, so the Opt-in form and the office signs for recruitment were developed and used.

In order for study results to be generalized, the diversity of the participants needs to match that of the specific population being studied; however, in the HEAT study, the African American and Hispanic populations were under-represented. Caucasians with arthritis in the general population are represented by 40.1%, African Americans 48.6%, and Hispanics 44.3%. Asians were not reported (Barbour, 2017). Regarding gender, from 2013-2015 the estimated prevalence of arthritis in the United States was 43.8% for women and 38.5% for men. In the HEAT study, men represented 20% and women represented 80% of the total sample, with men randomized entirely to the EAT intervention group. A more evenly distributed gender sample with males represented in both groups would be desirable.

Screening Implementation

Screening procedures are not reported in EAT literature. This is an issue, because differences in approach could alter the recruitment results. The HEAT study's flexibility in location of the initial screening meeting was received positively for recruitment but added a variable not controlled in the protocol. The initial measurements were usually obtained at the participant's home or work on the participant's floor or bed. The change from hard to soft surfaces could impact the ROM baseline measurements. After inclusion criteria were met during the screening process and the explanations of the study parameters, most participants displayed interest in the idea of using horses to help arthritis, but a few were shocked at the idea. Drawing blood draw from participants was initially believed by the PI to be a potential barrier; however, this was not an issue for any participants. Most participants said they were used to needles and were therefore comfortable with this

procedure. Overall the screening process was very successful and the screening protocols were adhered to without problems. Feasibility for screening and recruiting per protocol was achieved.

Intervention Implementation

The next feasibility variable was implementation of the intervention procedures based on the proposed protocol. No other EAT study for physical disabilities is known to have reported fidelity procedures (White-Lewis et al., 2017). Without fidelity monitoring, it is unknown that the intended protocol and the delivered protocol are the same. This can introduce confounding variables that are not accounted for in the study results (Czajkowski, 2011) and invalidate or make the results suspect.

Successful procedures included phone communication, the EAT intervention protocol, and the ExEd intervention protocol. Communication phone calls with participants, waiting for a full cohort to begin the intervention, and reminder phone calls prior to the interventions were received well. The participants anticipated the calls and often stated their appreciation of the reminder. The experimental and control interventions were implemented with only a few minor deviations. The EAT protocol required participants to be available on a specific day (Friday) and time (5:30 p.m.), and they attended each time except for one participant who had a previously scheduled vacation. The ExEd protocol was more flexible, allowing participants to choose their education day of the week as a cohort as long as it was within seven days of the EAT intervention. This too was successful, except for illness. This supports the study protocol timing and procedures. Attendance would have suffered if the interventions were burdensome or uninteresting. Fidelity was observed and maintained by the RAs and the PI without incident as evidenced by no protocol implementation violation

forms completed. This form was to be completed if a major break in protocol had occurred, such as a participant injury or a deviation from the protocol for more than 15 seconds.

Several anticipated problems did not become issues. Anticipated exposure to heat and cold with older adults did not result in attrition or absenteeism. For bonding purposes, the horse-rider match remained the same throughout the intervention, and no horses were unable to complete their interventions with their assigned human partners. This is a potential problem if a therapeutic riding center has many customers who need use of the therapy horses. This is evidence that the intervention procedures implemented were feasible and acceptable. Participants complied with the protocols by remaining for the one hour EAT or ExEd sessions, completing the measurement tools, and following instructions from the PATH-certified riding instructor or ExEd instructor. Only minor variations in the EAT protocol occurred with one participant trotting for three steps (less than 15 seconds) and another who was initially fearful of horses but wanted to participate despite this minor fear, stood in two-point for ten seconds longer than was asked. This was viewed as a positive sign that her fear of horses was diminished to the point that she wanted to be proud of her accomplishments. These particular participants stated they were having such a positive experience that they wanted to increase their activity level.

Attrition

Attrition was low, at 0.5% compared with 31 similar studies with an average attrition of 20% (White-Lewis et al., 2017). No mention of bonding time in the 31 studies was reported. In the HEAT study, the low attrition may have been attributed to the human-animal bonding time that was provided at the end of the EAT sessions. Human-animal bonding is well documented in the literature and was evident at the EAT group sessions

(Hausberger, Roche, Henry, & Visser, 2008; Sawaryn, 2008; Yorke et al., 2008).

Socialization was observed to be enjoyed by both groups each week (Cornwell, Laumann, & Schumm, 2008). Several participants mentioned that they were homebound with their arthritis and the study allowed them a chance to “venture outside.” Many smiles and outward signs of pleasure were noted in both intervention groups.

Measurements

All measurements were completed within the designated time frame except for measurements of one participant whose joints were measured prior to week 4 instead of after the week 3 EAT intervention. Range of motion measurements at the barn had been completed in a private room on the floor with a sheet placed for cleanliness. This participant felt she could not bend down to the floor or stand up after measurements. The next week (week 4), a sturdy picnic table was obtained and covered with a sheet for that participant to lie down on without having to bend all the way to the floor. This deviated from protocol with measurements for this participant completed prior to the week 4 intervention. A suitable place, rather than the floor of a private room at the barn or the floor at Saint Luke’s College, would have been received better. In the systematic review by White-Lewis (2017), the specific time frame for measurements compared with the intervention from the study was not reported. For internal validity, it is important to report the measurement timing compared to the intervention. If a long period of time occurs after the intervention and before measurement, then confounding influences can alter the results. Additionally, the reasons the measurements were postponed should be listed to aid future researchers of similar research studies in developing protocols and procedures without delays.

Acceptability of the Study Protocol

Acceptability was defined as how the participants reacted to the study protocol (Bowen et al., 2009). The study protocols were acceptable as evidenced by the high attendance and low attrition of the participants in both groups. Additionally no complaints were received from either the intervention or control groups. The longitudinal effects of the EAT was that the participants did not intend to continue with the EAT intervention after the study. Although the reasons were not reported and measured, several participants anecdotally stated that the cost of \$40/hour was too expensive to continue. No EAT studies were found to have investigated the cost benefit of therapeutic riding, hippotherapy, or equine-assisted therapy. If third party payers would include EAT as a recognized treatment, more people would likely benefit. Since 2015, Canada's government insurance has been paying for equine therapy for post-traumatic stress disorder in veterans (Madan, 2015). The EAT participants in this study may have continued if the costs were covered by insurance, though they were not specifically asked. Four inquired about renting horses for unsupervised riding from the Therapeutic Riding Center. This was not an option at this facility. Two participants stated they loved riding the horses and felt six weeks was too short a duration for the study.

Dependent Variables

Pain and ROM

Pain and ROM showed improvement. EAT significantly decreased pain in the back, hips, and shoulder and increased ROM for backs and hips over time. ROM did not significantly improve in the backs and hips of the control group. Movement is known to improve joint pain (Graham, Kremer, & Wheeler, 2008; Hughes et al., 2015), and EAT has a

unique tri-rotational movement that could account for the improvements (Selby & Smith-Osborne, 2013). Increases in core strength reported by Araujo et al. (2011) in older adults, caused by the horse's movement over uneven ground, contribute to the improvements. The significant decrease in pain may result in long term maintenance of exercise regimes (Resnick et al., 2014). In the HEAT study the decrease in pain was due to increased ROM and muscle strength. Which muscles were affected would need further study, but based on previous research and the intended exercise regimes, the leg, trunk, arms, and back were all affected.

Knee pain did not improve statistically with six weeks of EAT and was the only non-significant pain outcome measure within the EAT group. This may be due to the EAT curriculum not requiring much knee movement with the horses at a walk. The knee movement of the rider in a walking horse is minimal. Also weight bearing with the two-point exercise would put increased pressure on the knees and may have contributed to non-significant findings. When a horse is trotting and the rider is posting (standing and sitting with each trot step of the horse) the knees are engaged in increased activity. In reviewing other exercise studies targeting knees, eight weeks of hydrotherapy did produce significant pain decrease for fifteen adult patients with arthritis (Karimi & Rahnema, 2016). The hydrotherapy provides non weight-bearing exercise on the participant's knees, unlike the horse riding in two-point that could have placed stress on the knee joint. Future research could study the differences in knee pain outcomes comparing walking and a posting trot to assess improvement.

When compared to other ROM exercise therapies that improve symptoms of arthritis, results from Bieler, Siersma, Magnusson, Kjaer, and Beyer's (2018) study of older

adults exercising for four months using Nordic walking, physiotherapy, and home exercise regimes have similar outcomes. EAT's ability to relax the participant's hips with the rhythmic motion of the horses may have accounted for the significant changes. One EAT participant at baseline reported she could not walk more than ten steps due to hip pain and stiffness. After two EAT sessions, she claimed she could go to the store, had completed shopping for food, and had resumed activities of daily living that she had not been able to for years.

Quality of Life

The EAT group had improved QOL scores for upper limb, lower limb, and affect but not for symptoms of arthritis pain or social interaction. Comparatively, QOL was considered in a four-week randomized controlled trial for arthritis in adult participants in their 50s and 60s, that measured dynamic exercise compared to conventional joint treatment (Baillet et al., 2009). At four weeks these authors found no significant improvement in the AIMS2 scores. The HEAT study found significant improvement for upper limb, lower limb, and affect QOL outcomes for the EAT group. The six weeks of EAT intervention could have produced a more measureable effect resulting in improved AIMS-2 scores. Conflicting results in the HEAT study on the AIMS-2 symptoms category (which is defined as arthritis pain) and the VAS results were found. The AIMS-2 was not statistically significant for decreased pain but the VAS was. The AIMS2 may not have been sensitive enough or specific enough to measure the symptoms (arthritis pain) as efficiently as the VAS, or the dose may not have been long enough to affect limb pain in everyday life tasks but did in the short term reporting of pain. The improvements in affect found in this study was similar to the findings of Pretty et al. (2007), who reported significant improvement in affect when

riding horses. A suggestion of more than one QOL measure for adults with arthritis could be used in future research to verify self-reported findings and correlate the results.

Enjoyment of Nature – Environment

The Environmental Inventory Scale assessed enjoyment of nature. Unfortunately, several questions specified nature as wilderness. For people with ambulating challenges, the idea of ambulating in untamed wilderness created negative reactions. Brooks, Ottley, Arbuthnott, and Sevigny (2017) compared indoor exposure to outdoor exposure in actual experience and with pictures. They found that actual experience with nature improved mood as opposed to the HEAT study findings. Their study had the participants walk for ten minutes, but the setting of the exercise was not mentioned. Improved tool selection assessing the human-animal interaction and the environment of the barn was not found. This is an opportunity for tool development specific to EAT research.

Biomarkers COMP and Troponin T

The values obtained at baseline and at six weeks were so variable they were not statistically significant. Pereira Nunes Pinto et al. (2017) stated that COMP increases immediately (no time limit is specified) after exercise. Although the blood was drawn right after the intervention in week six, it was drawn at different times after riding, post grooming, and after bonding with the horses, which varied with different participants and how many treats they fed the horses. This may have delayed the blood draw enough to not be considered immediate and produce an inaccurate reading. The levels of COMP and troponin T may not have changed drastically enough in the intervention period to be measured by the ELISA assay. The dose or duration of the EAT intervention may not have been long enough or frequent enough to cause a reaction in muscle and cartilage. Another possibility is that

the sensitivity and specificity of COMP and troponin T is not appropriate for this amount or type of exercise.

One participant started a new job right after the beginning of the study. Her new employment was at an antique store that required climbing stairs many times each day. Her troponin percent change from baseline to six weeks was 2939%. The closest percent change in any other participant in the study was 303%. This large increase may have been due to the increase in muscle usage with climbing stairs daily in the new job. This was a change from the self-reported sedentary life she led prior to the new position. This demonstrates that a considerable change in exercise does produce an increase in troponin T. This can be interpreted that the changes in muscles with horse walking may not produce enough troponin T to be read by the ELISA assays. These biomarkers may not be sensitive or specific enough for the minute muscular and cartilage changes resulting from EAT research and should be reconsidered as an outcome variable.

Adverse Events

One participant suffered hip pain after the first EAT session. She stopped and discontinued the study after consulting her physician. There were no other instances of harm noted. Anecdotally several participants were tearful on the last night of the EAT intervention. They were tearful because they were leaving their EAT horse. Separation anxiety after forming the human-equine bond was an anticipated risk mentioned in the consent. One participant from another cohort returned to watch and visit the horses and handlers during the second cohort. She did this with permission from the cohort participants. A picture of the participant and their horse was sent by email to each participant in an attempt to lessen this separation anxiety. Each participant was also given

an opportunity to continue EAT using their previously assigned horse at their own expense. No participants opted to continue EAT. Participants were given the option of visiting the horses at any time. Only the one participant came back to the therapeutic riding stables after their intervention session was finished. No follow-up was conducted to measure visitation after the end of the study period. Horse rental was not an option at this riding stables but was requested by three participants. No horse rental stables are within one hour of Kansas City, Missouri or Kansas City, Kansas. Horse riding was offered and rejected as an option by the three participants who asked about it. The ethical dilemma of removing a beneficial equine therapy at the end of a study presents opportunities for improvement of protocols in future research.

Overall Impressions of the Study

The last question on the exit survey was an open-ended question with suggestions to improve the study. Comments on were all positive such as “had a good time,” “wonderful experience,” and “the benefits were/are extraordinary.” One participant felt so strongly about the benefits that she wrote a poem to commemorate the positive feelings. A study design suggestion from the one participant with the original fear of horses was to have a longer study duration with a two-month break and then another six-week intervention. Assessing maintenance of perceived benefits longitudinally could be a protocol improvement. It would have been desirable to complete a follow-up phone call or physical measurements at one, three, and six months to assess the maintenance of any benefits.

Limitations

This was a feasibility and acceptability study of a convenience sample. Although threats to internal and external validity were partly mitigated with blinding, randomization,

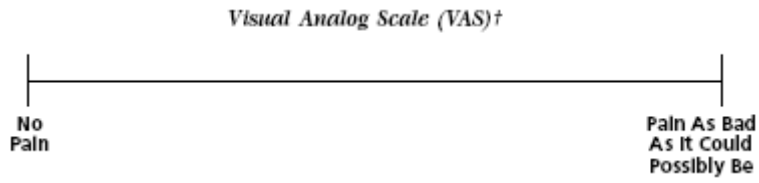
and consistency in horses and personnel, cautious interpretation of the results is warranted. Threats to external validity include small sample size, fewer male participants in the control group, and underrepresentation of African American and Hispanic arthritis populations. Threats to internal validity include several factors. First, the PI was unable to control for extraneous exercise in study participants over the six-week period. An increase in moderate exercise introduced during the study period could produce inaccurate positively significant results due to the additional extraneous exercise. Very strenuous exercise could also produce positive results, or, if wearing on the joints and muscles, it could produce negative results. Either condition confounds the accuracy of the results and was not accounted for in this study. Second, the PI was unable to mask her positive feelings about both of the interventions without a way to quantify those reactions and compare the effects on the participants. The PI could have inadvertently expressed more intense positive feelings about one intervention over the other. This would create a Hawthorne effect and result in biased results. Third, potentially confounding variables such as participant illnesses and differences in diet over the study period were not accounted for. Each can have a systemic effect and affect results. Fourth, previous horse riding experience of participants was not measured nor were the participant views of human-animal relationships measured. Previous exposure and views can alter present interpretations. Fifth, the gender discrepancy – with men represented only in the experimental group due to randomization – could confound the significant results found from the EAT. Men's muscles and joints might improve faster than women's when reacting to EAT. These factors could have altered the results, so caution should be used when applying these findings in a clinical setting.

Another limitation is that the EAT curriculum was not specific to the participant's arthritis pain/stiffness sites but was the same for all participants. Future research could create a curriculum to support specific symptom groups such as symptoms in backs, knees, shoulders, and hips. The curriculum and riding therapy could be developed to target specific symptoms for improvement specific to those areas.

Conclusion

The information in this study informs the science of human-animal interactions and contributes to the growing knowledge of the benefits of EAT in adults with arthritis. The protocols and procedures were successfully delivered by the PI and RA. The significant exploratory results need to be interpreted cautiously due to the limited sample size and the lack of sample diversity. Future research should include large multi-center trials, increased sample diversity, and use of a reliable and valid measure for the environment associated with EAT. Comparing effects from different doses and duration of riding would inform the EAT science and future designs. A cost-benefit analysis study could support the use of EAT as a valid therapy for clinical use with a potential for third-party insurance reimbursement, or if the cost is found to be too expensive compared to medication and other exercise regimes, then alternative ways of delivering EAT such as mobile EAT, could be tested. Continued high quality randomized controlled trials need to be the standard for testing EAT's impact on individual outcomes.

APPENDIX A
VISUAL ANALOG SCALE



(Boonstra et al., 2008; Hawker et al., 2011; Physiopedia, n.d.)

APPENDIX B

AIMS-2 SF ARTHRITIS IMPACT MEASUREMENT SCALES 2 SHORT FORM

AIMS-2 SF
ARTHRITIS IMPACT MEASUREMENT
SCALES 2 Short Form

INSTRUCTIONS : Please answer the following questions about your health.
Most questions ask about your health during the past 4 weeks.
There are no right or wrong answers to the questions and most can be answered with a simple check (✓).
Please answer every question.

<i>DURING THE PAST 4 WEEKS ...</i>	All days	Most days	Some days	Fews days	No days
1. How often were you physically able to drive a car or use public transportation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. How often were you in a bed or chair for most or all of the days ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Did you have trouble doing vigorous activities such as running, lifting heavy objects, or participating in strenuous sports ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Did you have trouble either walking several blocks or climbing a few flights of stairs ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were you unable to walk unless assisted by another person or by a cane, crutches, or walker ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Could you easily write with a pen or pencil ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Could you easily button a shirt or blouse ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Could you easily turn a key in a lock ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>					
9. Could you easily comb or brush your hair ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Could you easily reach shelves that were above your head ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Did you need help to get dressed ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Did you need help to get in or out of bed ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

AIMS2 SF 1.3 - Quality of Life Group in Rheumatology, France 1995. Arthritis & Rheumatism 1997; 40: 1267-74
Adaptation from AIMS2 - R. Meenan - Boston, Ms

DURING THE PAST 4 WEEKS

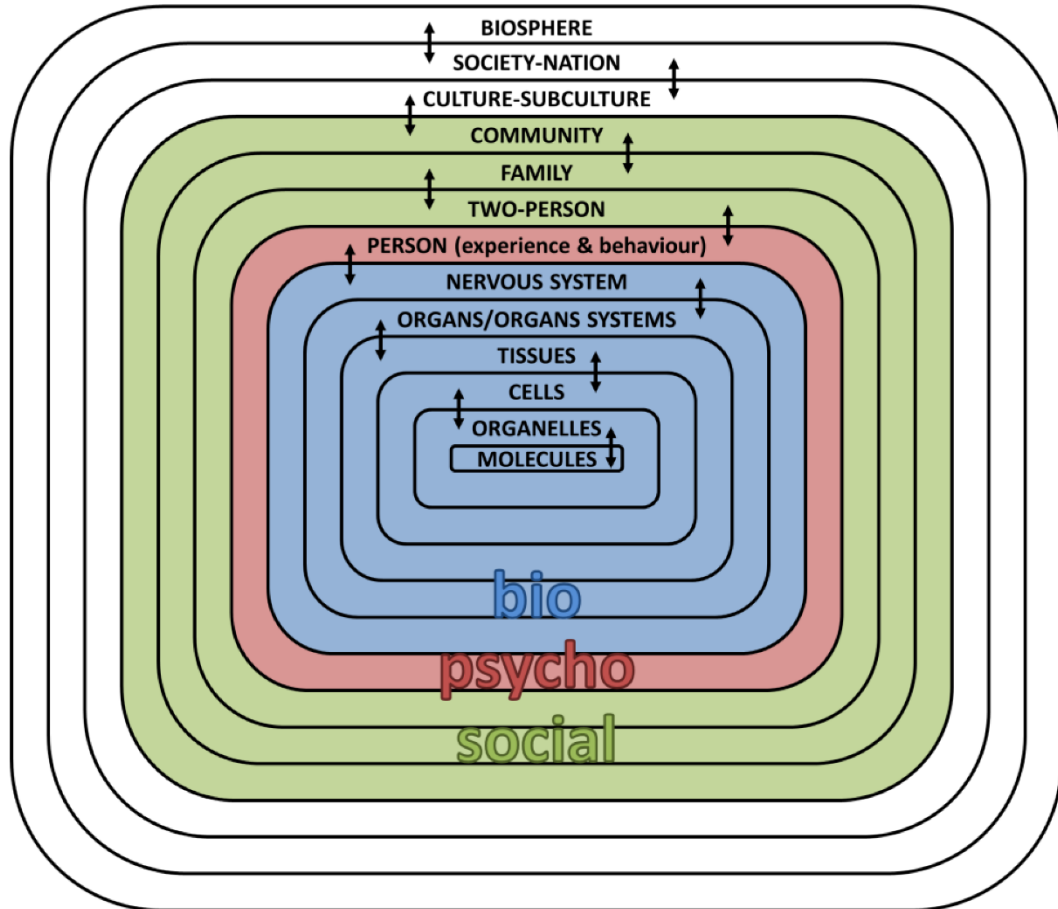
	All days	Most days	Some days	Few days	No days
13. How often did you have severe pain from you arthritis ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. How often did your morning stiffness last more than one hour from the time you woke up ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. How often did your pain make it difficult for you to sleep ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Always	Very often	Some times	Almost never	Never
16. How often have you felt tense or high strung ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. How often have you been bothered by nervousness or your nerves ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

18. How often have you been in low or very low spirits ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. How often have you enjoyed the things you do ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. How often did you feel a burden to others ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	All days	Most days	Some days	Few days	No days
21. How often did you get together with friends or relatives ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. How often were you on the telephone with close friends or relatives ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. How often did you go to a meeting of a church, club, team or other group ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Did you feel that your family or friends were sensitive to your personal needs ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>If you are unemployed, disabled or retired, END of questionnaire.</i>	All days	Most days	Some days	Few days	No days
25. How often were you unable to do any paid work, house work or school work ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. On the days that you did work, how often did you have to work a shorter day ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

AIMS2 SF 1.3 - Quality of Life Group in Rheumatology, France 1995. Arthritis & Rheumatism 1997; 40: 1267-74
Adaptation from AIMS2 - R. Meenan - Boston, MA

APPENDIX C

ENGEL'S BIOPSYCHOSOCIAL MODEL, DEBUSE'S MODEL, AND PROPOSED EAT MODEL

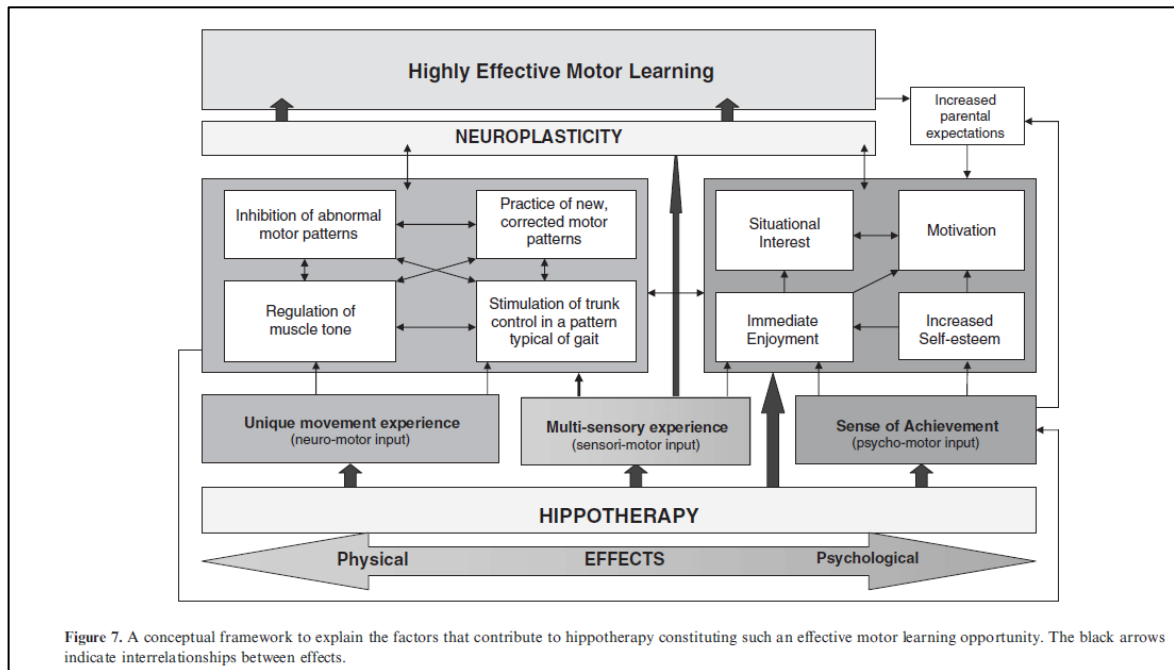


(Engel, 1977)

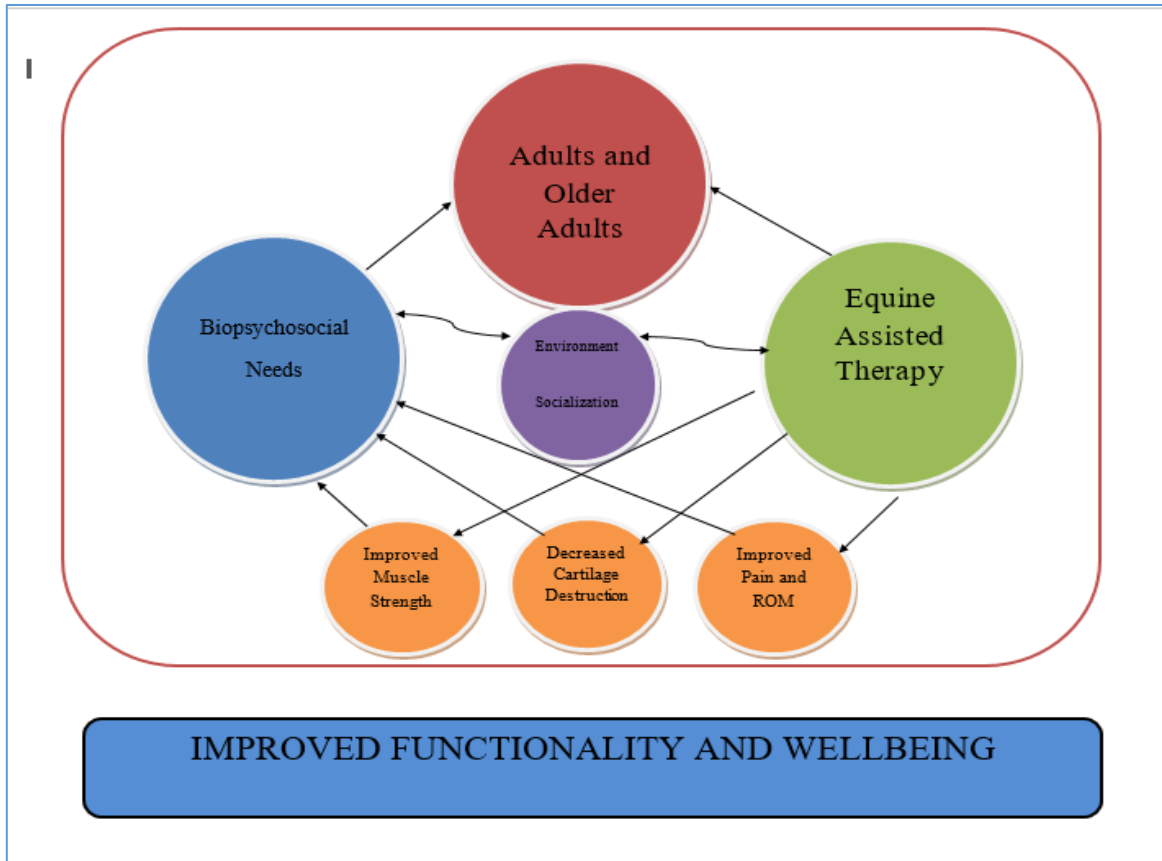
This model views health issues focusing on cellular components and expanding in increments to the biosphere.

- Molecular or cellular level will be evaluated with biomarkers.
- Organ and orthopedic system levels will be assessed with goniometer readings.

- Person level will be assessed by the PI appraising the unique tri-rotational movements of the horse (Selby & Smith-Osborne, 2013) affecting the rider's spine and hip movements – video tape review.
- Family and community, the next expansion of the model, depict a larger group effect. Support systems are assessed by the social subcategory of the Arthritis Impact Measuring Scale 2 tool (AIMS-2).
- Culture/subculture, society and biosphere. The HEAT study quantified the environmental effect by use of the Environmental Attitudes Inventory Scale.



Debusse Conceptual Framework (Debusse et al., 2009)



Equine-Assisted Therapy for Arthritic Adults and Older Adults Model

APPENDIX D

EQUINE-ASSISTED THERAPY FOR ADULTS AND OLDER ADULTS

WITH ARTHRITIS EAT INTERVENTION GROUP CURRICULUM

Definition of Terms

2-beat trot: A steady gait in which the horse springs from one diagonal footing to the other. In between these springs, all four legs are off the ground.

2-point position: Participant leans slightly forward with buttocks off of saddle, holding reins or saddle.

At the rail: Along the arena wall.

At the walk: Horse is walking.

Gait Belt: A thick belt used to stabilize during ambulation.

Girth: Band connecting one side of saddle to the other under horse's belly.

Halt: Causing the horse to stop moving.

Long-line: A long lead rope fastened to the horse's bridle so the horse leader can have control while allowing the participant to handle the reins.

Pommel: Upper front part of a riding saddle.

Reins/Reining: (noun) Item of tack used to guide or steer the horse. (verb) Act of steering the horse.

Tack/Tacking: (noun) A piece of equipment or accessory for a horse such as a blanket, saddle, bridle and reins. (verb) Act of putting the equipment on the horse.

Track right: Horse moves around the riding arena to the right.

Track left: Horse moves around the riding arena to the left.

Walk-on: Cause the horse to move forward.

Week	Lesson	Task completed as stated (X) /correction required (C)
Lesson Plan Week #1	Welcomes, introductions, safety briefing, tacking, grooming, initial ride	
Welcome to the Therapeutic Riding Center	Brief tour, bathrooms, safety issues in barn, where to put personal items, where participants wait for the certified riding instructor, horse leader, side-walkers, other assistants (e.g., riding stable volunteers who work with the horses), assist with helmet, and belt if necessary.	
Safety	Grooming & Safety: Grooming & safety instruction based on the Pony Club Safety Booklet – 2017 (USPC Safety Committee, 2017).	
	Participants will be taken into barn where horses are tied or held by a horse leader.	
	Participants learn safety precautions on approaching and moving around equines, body parts, horse psychology, and interact with horses	
	Demonstration to the participant on grooming with soft brushes, checking head, body, legs of horse	

Week	Lesson	Task completed as stated (X) /correction required (C)
	Participants learn and practice tacking (pad, saddle, girth, and reins) and note importance of proper position of equipment for rider balance, horse movement, and comfort. Assistance with saddling if necessary.	
Mounting	Demonstration and proper horse mounting from stairs, ramp, or steps to the participant.	
	Participants mount their horse.	
	Each participant will have a horse leader and two side-walkers initially (1-3 weeks). If the participant has previous equine experience, the first week will include a leader with a long-line for safety while the participant demonstrates steering of the horse. The certified riding instructor in collaboration with the principal investigator will determine level of safety and assistance needed as well as potential for progression to future independence.	
	After each participant has mounted on their horse they are led by a horse leader to the center of the arena and halt until all participants are mounted. They will wait for directions from the certified riding instructor.	
Warm-up Exercises	Horse leaders hold the reins and lead the horses from the center of the arena, or have a long-line attached to the bridle to assure safety for those riders that demonstrate steering proficiency, and will track right at the walk. Participants will experience the walking of the horse.	
	<p>All participants' warm-up exercises will be completed with the horse walking. Each movement is repeated 5 times.</p> <ul style="list-style-type: none"> • Head rotations turn head left and right • Shrug shoulders up back and down • 1 arm up, 1 arm down • Arms out to side, trunk rotations 	
	<p>Horse leader turns horse to walk in opposite direction, or assure safety in turning with the long-line for those riders that demonstrate steering proficiency.</p> <ul style="list-style-type: none"> • Take feet out of stirrups, lift knee up, then lower, repeat with opposite leg • 1 leg forward, 1 leg back and alternate • Toes up, toes down • Make circles with ankles • Place feet back in stirrups with assist if needed 	
Riding Exercise	Participants ride along arena wall once in each direction. Leader and side-walkers will accompany participant. Horse leaders ensure that horses and participants are equally spaced around the arena.	
Cool Down	Participants continue riding along the arena wall with their feet out of the stirrups.	
Dismount/ Closure	Participants walk their horse to the center of the arena, line up, and halt. Participants thank the horse by petting and talking to the horse and thank the volunteers.	
	Participants dismount one at a time to the ground, ramp or mounting stairs with the certified riding instructor's assistance and supervision.	
	Participants may assist with loosening girth and are allowed petting/bonding/social time with horse from the ground (horse leader is present and horse may be given treats if appropriate).	

Week	Lesson	Task completed as stated (X) /correction required (C)
	Participants may also assist with leading the horse back to stall or prep area with horse leader.	
Lesson Plan Week #2	Reinforce lessons from Week #1	
Welcome to the Barn	Certified riding instructor, horse leader and side-walkers greets participant, assist with helmets, belts if necessary, and accompany into barn.	
Grooming and Safety	Participants join the horse leader in the barn where the horses are tied or held by the horse leader. Certified riding instructor reviews Week 1 safety precautions and familiarization with horse.	
	Certified riding instructor continues teaching the grooming skills using various brushes, with the participant. Participants progress from grooming with verbal or physical assistance to independence with stand-by assistance from the certified riding instructor.	
	The participants will tack the horse (pad, saddle, girth and reins) with progression from tacking with verbal or physical assistance from the certified riding instructor to independence with stand-by assistance. Certified riding instructor will continue to note importance of proper position of equipment for rider balance, horse movement, and comfort.	
Mounting	Demonstration and proper horse mounting from stairs, ramp, or steps from the certified riding instructor to the participant.	
	Participants repeat the process verbally then mount the horse.	
	Each participant will have a horse leader and 2 side-walkers initially (1-3 weeks). If the participant has previous equine experience the first 3 weeks will include a leader with a long-line for safety while the participant demonstrates steering of the horse. The certified riding instructor in collaboration with the principal investigator will determine level of safety and assistance needed as well as potential for progression to future independence.	
	After each participant has mounted on their horse they are led by a horse leader to the center of the arena and halt until all participants are mounted. They will wait for directions from the certified riding instructor.	
Warm-up Exercises	Horse leaders will lead the horses from the center of the arena unless in week one it is determined that the participant can steer the horse independently in which case a long-line will be used and the horse leader will walk along side of the participant assuring safety. The participant/horse will track right at the walk. Participant will experience the walking of the horse.	
	All participants' warm-up exercises will be completed with the horse walking. Each movement is repeated 5 times. <ul style="list-style-type: none"> • Head rotations turn head left and right • Shrug shoulders up back and down • 1 arm up, 1 arm down • Arms out to side, trunk rotations 	
	Horse leader turns horse to walk in opposite direction. <ul style="list-style-type: none"> • Take feet out of stirrups, lift knee up, then lower, repeat with opposite leg • 1 leg forward, 1 leg back and alternate • Toes up, toes down • Make circles with ankles 	

Week	Lesson	Task completed as stated (X) /correction required (C)
	<ul style="list-style-type: none"> Place feet back in stirrups with assist if needed 	
Riding Exercise	Participants ride along arena wall twice in each direction. Leader and side-walkers will accompany participant. Horse leaders ensure that horses and participants are equally spaced around the arena.	
Cool Down	Participants continue riding along the arena wall with their feet out of the stirrups.	
Dismount/ Closure	Walk to the center of the arena, line up, and halt. Participants thank the horse by petting and talking to the horse and thank the volunteers.	
	Participants dismount one at a time to the ground, ramp or mounting stairs with the certified riding instructor's assistance and supervision.	
	Participant may assist with loosening girth and are allowed petting/bonding/social time with horse from the ground (horse leader is present and horse may be given treats if appropriate).	
	Participant may also assist with leading the horse back to stall or prep area with horse leader.	
Lesson Plan Week #3	Horse grooming, tacking, mounting, and lesson and warm-up progressing toward increased independence based on individual abilities determined by certified riding instructor in collaboration with principal investigator.	
Welcome to the Barn	Certified riding instructor, horse leader and side-walkers greet participants, assist with helmets, belts if necessary, and accompany into barn.	
Grooming and Safety	Participants join the horse leader in the barn where the horses are tied or held by a horse leader. Certified riding instructor reviews Week 1 and 2 safety precautions and familiarization with horse.	
	Certified riding instructor reviews grooming skills using various brushes with the participant.	
	Certified riding instructor helps the participant practice tacking (pad, saddle, girth and reins) and notes the importance of proper position of equipment for rider balance, horse movement, and comfort.	
Mounting	Demonstration and proper horse mounting from stairs, ramp, or steps to the participant if requested	
	Participants repeat the process verbally then mount the horse.	
	Each participant will have a horse leader and 2 side-walkers (1-3 weeks). If the participant has previous equine experience, the first 3 weeks will include a leader with a long-line for safety while the participant demonstrates steering of the horse. The certified riding instructor in collaboration with the principal investigator will determine level of safety and assistance needed as well as potential for progression to future independence.	
	After each participant has mounted on their horse they are led by a horse leader to the center of the arena and halt until all participants are mounted. They will wait for directions from the certified riding instructor.	
Warm-up Exercises	All participants' warm-up exercises will be completed with the horse walking. Each movement is repeated 5 times. <ul style="list-style-type: none"> Head rotations turn head left and right Shrug shoulders up back and down 1 arm up, 1 arm down Arms out to side, trunk rotations 	
	Horse leader turns horse to walk in opposite direction.	

Week	Lesson	Task completed as stated (X) /correction required (C)
	<ul style="list-style-type: none"> • Take feet out of stirrups, lift knee up, then lower, repeat with opposite leg • 1 leg forward, 1 leg back and alternate • Toes up, toes down • Make circles with ankles • Place feet back in stirrups with assist if needed 	
Riding Exercise	Participants build on all previous skills sets and learn use of reins, seat and legs for walk and halt, introduce to two-point position (balancing in your stirrups with standing halfway up). Participants may balance with the horn of the saddle if needed. Skills used in this lesson are from <i>101 Arena Exercises by Cherry Hill & US Pony Club Manual D</i> (Hill & Wennberg, 1995, p. 35)	
	Halt/walk Practice: -Practice halts at letters placed around arena (see diagram) count of 4 and Participants cue horse for walk on. -Practice walk/halt transitions 3 times covering half distance of arena between each halt.	
	Steering Practice: (Hill & Wennberg, 1995, p. 36) Teach steering around 5 cones placed 9 feet apart in a straight line on each side of the arena 4 times in each direction.	
	Two Point Practice: (Hill & Wennberg, 1995, p. 40) -Halt at a letter and certified riding instructor introduces the concept of two-point. Participant's weight is shifted off of the horse's spine. Participants stand up in two-point stirrups for count of 10, then sit, and horse walks on. The horn may be used to balance. -Halt again at same point in arena (participants may be cued to remember at which letter to halt) and repeat two-point for 10 count at halt. -Horse leaders assist a change of rein and walk on - tracking left and participants stand in stirrups at walk (two-point position) for 10 count, then sit. Halt at same point in arena. Participants may sit at any time they feel discomfort in their joints.	
Cool Down	Participant continue riding along the arena wall with their feet out of the stirrups.	
Dismount/ Closure	Walk to the center of the arena, line up, and halt. Participants thank the horse by petting and talking to the horse and thank the volunteers.	
	Participants dismount one at a time to the ground, ramp, or mounting stairs with the certified riding instructor's assistance and supervision.	
	Participant may assist with loosening girth and are allowed petting/bonding/social time with horse from the ground (horse leader is present and horse may be given treats if appropriate).	
	Participant may also assist with leading the horse back to stall or prep area with horse leader.	
Lesson Plan Week #4	Horse grooming, tacking, mounting, and lesson and warm-up progressing toward increased independence based on individual abilities determined by certified riding instructor in collaboration with principal investigator.	
Welcome to the Barn	Certified riding instructor, horse leader, and side-walkers greet participants, assist with helmets, belts if necessary, and accompany into barn.	
Grooming and Safety	Participants join the horse leader in the barn where the horses are tied or held by a horse leader. Certified riding instructor reviews Week 1, 2 safety precautions, and familiarization with horse.	

Week	Lesson	Task completed as stated (X) /correction required (C)
	Certified riding instructor reviews grooming skills using various brushes with the participant.	
	Certified riding instructor helps the participant practice tacking (pad, saddle, girth and reins) and notes the importance of proper position of equipment for rider balance, horse movement, and comfort.	
Mounting	Demonstration and proper horse mounting from stairs, ramp, or steps to the participant.	
	Participants repeat the process verbally then mount the horse.	
	Each participant will have a horse leader and two side-walkers if deemed necessary at this point for safety. The certified riding instructor in collaboration with the principal investigator will determine level of safety and assistance needed as well as potential for progression to future independence.	
	After each participant has mounted on their horse they are led by a horse leader to the center of the arena and halt until all participants are mounted. They will wait for directions from the certified riding instructor.	
Warm-up Exercises	<p>All participants' warm-up exercises will be completed with the horse walking. Each movement is repeated 5 times.</p> <ul style="list-style-type: none"> • Head rotations turn head left and right • Shrug shoulders up back and down • 1 arm up, 1 arm down • Arms out to side, trunk rotations 	
	<p>Horse leader turns horse to walk in opposite direction.</p> <ul style="list-style-type: none"> • Take feet out of stirrups, lift knee up, then lower, repeat with opposite leg • 1 leg forward, 1 leg back and alternate • Toes up, toes down • Make circles with ankles • Place feet back in stirrups with assist if needed 	
Riding Exercise	Participant builds on all skills sets and learn use of reins, seat, and legs for walk and halt, introduce to two-point position (balancing in your stirrups with standing halfway up). Participants may balance with the horn of the saddle if needed. Skills used in this lesson are from <i>101 Arena Exercises by Cherry Hill & US Pony Club Manual D</i> (Hill & Wennberg, 1995, p. 35)	
	<p>Halt/walk Practice:</p> <ul style="list-style-type: none"> -Practice halts at letters placed around arena (see diagram) count of 4 and Participants cue horse for walk on. -Practice walk/halt transitions 3 times covering half distance of arena between each halt. 	
	<p>Steering Practice: (Hill & Wennberg, 1995, p. 36)</p> <ul style="list-style-type: none"> -Teach steering around 5 cones placed 9 feet apart in a straight line on each side of the arena 4 times in each direction. 	
	<p>Two-Point Practice: (Hill & Wennberg, 1995, p. 40)</p> <ul style="list-style-type: none"> -Halt at a letter placed on arena wall and demonstrate two-point. - Stand up in two-point stirrups and horse walks to a count of 10, sit to a count of 10, two-point to a count of 10, sit to a count of 10, halt horse, count to 10, walk on, and repeat in reverse order. 	

Week	Lesson	Task completed as stated (X) /correction required (C)
	-Horse leaders assist a change of direction and walk on tracking left and participants stand up in two-point stirrups and horse walks to a count of 10, sit to a count of 10, two-point to a count of 10, sit to a count of 10, halt horse, count to 10, walk on, and repeat in reverse order. The horn may be used to balance. Halt at same point in arena. Participants may sit at any time they feel discomfort in their joints.	
Cool Down	Participants continue riding along the arena wall with their feet out of the stirrups.	
Dismount/ Closure	Walk to the center of the arena, line up, and halt. Participants thank the horse by petting and talking to the horse and thank the volunteers.	
	Participants dismount one at a time to the ground, ramp, or mounting stairs with the certified riding instructor's assistance and supervision.	
	Participants may assist with loosening girth and are allowed petting/bonding/social time with horse from the ground (horse leader is present and horse may be given treats if appropriate).	
	Participants may also assist with leading the horse back to stall or prep area with horse leader.	
Lesson Plan Week #5	Build on skill sets from previous lessons, achieve connection of cues through turns and transitions with equine partner, and develop balance and strength in two-point, practice of right and left turn with simple change of direction and introduction of a lengthening walk. Skill progression based on individual abilities as determined by certified riding instructor in collaboration with principal investigator.	
Welcome to the Barn	Certified riding instructor, horse leader and side-walkers greet participants, assist with helmets, belts if necessary, and accompany into barn.	
Grooming and Safety	Participants join the horse leader in the barn where the horses are tied or held by a horse leader. Certified riding instructor reviews Week 1 safety precautions and familiarization with horse.	
	Certified riding instructor reviews grooming skills using various brushes with the participant.	
	Certified riding instructor helps the participant practice tacking (pad, saddle, girth and reins) and notes the importance of proper position of equipment for rider balance, horse movement, and comfort.	
Mounting	Demonstration and proper horse mounting from stairs, ramp, or steps to the participant.	
	Participants repeat the process verbally, then mount the horse.	
	Each participant will have a horse leader and two side-walkers initially (1-3 weeks). If the participant has previous equine experience the first week will include a leader with a lead-rope for safety while the participant demonstrates steering of the horse. The certified riding instructor in collaboration with the principal investigator will determine level of safety and assistance needed as well as potential for progression to future independence.	
	After each participant has mounted on their horse they are led by a horse leader to the center of the arena and halt until all participants are mounted. They will wait for directions from the certified riding instructor.	
Warm-up Exercises	<ul style="list-style-type: none"> • Head rotations turn head left and right 2 times • Shrug shoulders up back and down 2 times • 1 arm up, 1 arm down 2 times 	

Week	Lesson	Task completed as stated (X) /correction required (C)
	<ul style="list-style-type: none"> • Right arm reaches to touch right foot or as far as can comfortably reach, left arm reaches to touch left foot or as far as can comfortably reach 5 times each side • Right arm reaches to touch left foot or as far as can comfortably reach, left arm reaches to touch right foot or as far as can comfortably reach. 5 times each side • Arms out to side, trunk rotations • Take feet out of stirrups, lift knee up, then lower, repeat with opposite leg • 1 leg forward, 1 leg back and alternate • Toes up, toes down • Make circles with ankles • Place feet back in stirrups with assist if needed 	
Riding Exercises	Participants will track right at a walk. Horse leaders may not be necessary at this point but will observe and verbally instruct the rider on equal spacing between horses around the arena. The certified riding instructor will explain the how's, what's, and why's of each skill.	
	Halt/walk practice: -Participants will practice halts at 4 various obstacles placed around arena and perform an activity at each obstacle then walk on, do 2 times in each direction. Throw basketball in net Hook ring on a pole Place object in a bucket Throw bean bag at a target	
	Steering practice: (Hill & Wennberg, 1995, p. 36) -Participants will practice reining around 4 cones placed opposite each other in arena sides going from 1 cone to the opposite cone making a 4-loop serpentine (S-pattern) across the arena demonstrating a change of reins across the arena.	
	Two-Point Practice: (Hill & Wennberg, 1995, p. 40) -Participants stand up in two-point stirrups and walks to a count of 10, sit to a count of 10, two-point to a count of 10, sit to a count of 10, halt horse, count to 10, walk on, and reverse and repeat. -Participant begins new exercise tracking right and stands in two-point for one half of a lap around the arena correcting balance and maintaining position. Participant changes direction and repeats two-point one half lap again on the left rein. Participants may sit at any time they feel discomfort in their joints.	
	Practice lengthening the walk and shortening the walk in a sitting position. Participant will be taught to relax the reins and allow the horse's head to drop and walk to lengthen for 10 strides then shorten their grip on the reins and apply slight pressure from their legs to collect the horse into a collected walk for 10 steps. This will continue once around the arena then a change of direction and repeated tracking left for once around the arena. Both directions will be repeated twice.	
Cool Down	Participants continue riding along the arena wall with their feet out of the stirrups.	
Dismount/ Closure	Walk to the center of the arena, line up, and halt. Participants thank the horse by petting and talking to the horse and thank the volunteers.	

Week	Lesson	Task completed as stated (X) /correction required (C)
	Participants dismount one at a time to the ground, ramp, or mounting stairs with the certified riding instructor's assistance and supervision.	
	Participant may assist with loosening girth and are allowed petting/bonding/social time with horse from the ground (horse leader is present and horse may be given treats if appropriate).	
	Participant may also assist with leading the horse back to stall or prep area with horse leader.	
Lesson Plan Week #6	Build on all skill sets, achieve connection of cues through turns and transitions with equine partner, develop balance and strength in two-point, continue steering with simple change of direction, two-point position, lengthening and collecting the walk. New skill of backing the horse will be introduced. Skill progression based on individual abilities as determined by certified riding instructor in collaboration with principal investigator.	
Welcome to the Barn	Certified riding instructor, horse leader, and side-walkers greet participant, assist with helmets, belts if necessary, and accompany into barn.	
Grooming and Safety	Participant joins the horse leader in the barn where the horses are tied or held by a horse leader. Certified riding instructor reviews Week 1 safety precautions and familiarization with horse.	
	Certified riding instructor reviews grooming skills using various brushes with the participant.	
	Certified riding instructor helps the participant practice tacking (pad, saddle, girth, and reins) and notes the importance of proper position of equipment for rider balance, horse movement, and comfort.	
Mounting	Demonstration and proper horse mounting from stairs, ramp, or steps to the participant.	
	Participant repeats the process verbally, then mounts the horse.	
	Each participant will have a horse leader and two side-walkers initially (1-3 weeks). If the participant has previous equine experience the first week will include a leader with a long-line for safety while the participant demonstrates steering of the horse. The certified riding instructor in collaboration with the principal investigator will determine level of safety and assistance needed as well as potential for progression to future independence.	
	After each participant has mounted on their horse they are led by a horse leader to the center of the arena or if has demonstrated proficiency then will steer the horse with the horse leader walking at the horse's head and then halt until all participants are mounted. They will wait for directions from the certified riding instructor.	
Warm-up Exercises	<ul style="list-style-type: none"> • Head rotations turn head left and right 2 times • Shrug shoulders up back and down 2 times • 1 arm up, 1 arm down 2 times • Right arm reaches to touch right foot or as far as can comfortably reach, left arm reaches to touch left foot or as far as can comfortably reach 5 times each side • Right arm reaches to touch left foot or as far as can comfortably reach, left arm reaches to touch right foot or as far as can comfortably reach. 5 times each side • Arms out to side, trunk rotations 	

Week	Lesson	Task completed as stated (X) /correction required (C)
	<ul style="list-style-type: none"> • Take feet out of stirrups, lift knee up, then lower, repeat with opposite leg • 1 leg forward, 1 leg back and alternate • Toes up, toes down • Make circles with ankles • Place feet back in stirrups with assist if needed 	
Riding Exercise	Participants will track right at a walk. Horse leaders may not be necessary at this point but will observe and verbally instruct the rider on equal spacing between horses around the arena. The certified riding instructor will explain the how's, what's and why's of each skill.	
	Halt/walk practice: -Participants will practice halts at 4 various obstacles placed around arena and perform an activity at each obstacle then walk on, do 2 times in each direction. Throw basketball in net Hook ring on a pole Place object in a bucket Throw bean bag at a target	
	Steering practice: (Hill & Wennberg, 1995, p. 36) -Participants will practice steering around 4 cones placed opposite each other in arena sides going from 1 cone to the opposite cone making a 4-loop serpentine (S-pattern) across the arena demonstrating a change of reins across the arena.	
	Two-Point Practice: (Hill & Wennberg, 1995, p. 40) -Participants stand up in two-point stirrups and walk to a count of 10, sit to a count of 10, two-point to a count of 10, sit to a count of 10, halt horse, count to 10, walk on, and reverse and repeat. -Participants begin new exercise tracking right and stand in two-point for one half of a lap around the arena correcting balance and maintaining position. Participant changes direction and repeats two-point one-half lap again on the left rein. Participants may sit at any time they feel discomfort in their joints.	
	Practice lengthening the walk and shortening the walk in a sitting position. Participant will be taught to relax the reins and allow the horse's head to drop and walk to lengthen for 10 strides, then shorten their grip on the reins and apply slight pressure from their legs to collect the horse into a collected walk for 10 steps. This will continue once around the arena then a change of direction and repeated tracing left for once around the arena. Both directions will be repeated twice. Participant will halt and be instructed to back the horse 1 step at a time for 5 steps.	
Cool Down	Participants continue riding along the arena wall with their feet out of the stirrups.	
Dismount/ Closure	Walk to the center of the arena, line up, and halt. Participants thank the horse by petting and talking to the horse and thank the volunteers.	
	Participants dismount one at a time to the ground, ramp, or mounting stairs with the certified riding instructor's assistance and supervision.	
	Participants may assist with loosening girth and are allowed petting/bonding/social time with horse from the ground (horse leader is present and horse may be given treats if appropriate).	
	Participants may also assist with leading the horse back to stall or prep area with horse leader.	

APPENDIX E

EXERCISE TRAINING FOR ADULTS WITH ARTHRITIS

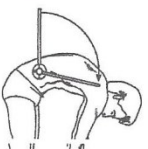


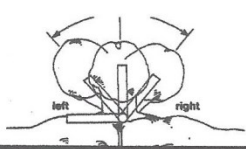


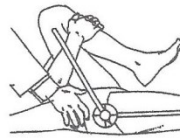

TASK	Task completed as stated (X) /correction required (C)	Time
Week #1		
Overview of arthritis		
How exercise helps how you feel		
How exercise helps keep you functioning		
The social and psychological benefits of exercise		
Week #2		
Benefits of stretching		
Exercise tips		
Endurance versus strength training		
Week #3		
How to exercise through the pain and why the hurt will help		
Workout tips		
How much is enough?		
Tools to use		
Week #4		
Workout intensity		
What a well rounded workout looks like		
Developing a plan		
Create a workout calendar		
Week #5		
Getting your doctor's OK		
Starting an exercise program		
Dos and Don'ts		
How do you keep it going after you start		
Week #6		
How to keep exercising interesting		
Keeping a log and tracking your progress		
High intensity exercises and arthritis		


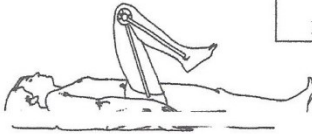
(How-to Exercise with Arthritis, n.d.)

APPENDIX F

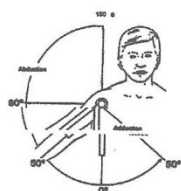
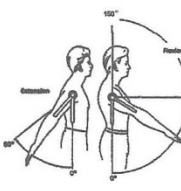
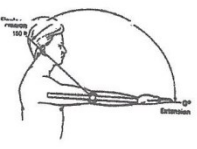
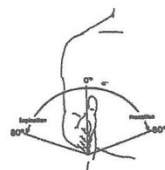

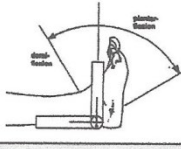
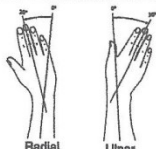

RANGE OF JOINT MOTION EVALUATION CHART


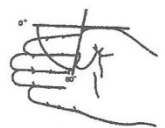


NAME OF PATIENT		CLIENT IDENTIFICATION NUMBER															
INSTRUCTIONS: For each affected joint, please indicate the existing limitation of motion by drawing a line(s) on the figures below, showing the maximum possible range of motion or by notating the chart in degrees. Provide a complete description of all affected joints in your narrative summary. If range of motion was normal for all joints, please comment in your narrative summary. If joints which do not appear on this chart are affected, please indicate the degree of limited motion in your narrative.																	
1. Back		2. Lateral (flexion)															
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;">Extension 25°</td> <td style="text-align: center; padding: 2px;">Flexion 90°</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Degrees</td> <td style="text-align: center; padding: 2px;">Degrees</td> </tr> </table>	Extension 25°	Flexion 90°	Degrees	Degrees		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;">Left 25°</td> <td style="text-align: center; padding: 2px;">Right 25°</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Degrees</td> <td style="text-align: center; padding: 2px;">Degrees</td> </tr> </table>	Left 25°	Right 25°	Degrees	Degrees						
Extension 25°	Flexion 90°																
Degrees	Degrees																
Left 25°	Right 25°																
Degrees	Degrees																
3. Neck		4. Neck (lateral bending)															
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;">Extension 60°</td> <td style="text-align: center; padding: 2px;">Flexion 50°</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Degrees</td> <td style="text-align: center; padding: 2px;">Degrees</td> </tr> </table>	Extension 60°	Flexion 50°	Degrees	Degrees		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;">Left 45°</td> <td style="text-align: center; padding: 2px;">Right 45°</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Degrees</td> <td style="text-align: center; padding: 2px;">Degrees</td> </tr> </table>	Left 45°	Right 45°	Degrees	Degrees						
Extension 60°	Flexion 50°																
Degrees	Degrees																
Left 45°	Right 45°																
Degrees	Degrees																
5. Neck (rotation)		6. Hip (backward extension)															
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;">Left 80°</td> <td style="text-align: center; padding: 2px;">Right 80°</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Degrees</td> <td style="text-align: center; padding: 2px;">Degrees</td> </tr> </table>	Left 80°	Right 80°	Degrees	Degrees		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;">Left 30°</td> <td style="text-align: center; padding: 2px;">Right 30°</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Degrees</td> <td style="text-align: center; padding: 2px;">Degrees</td> </tr> </table>	Left 30°	Right 30°	Degrees	Degrees						
Left 80°	Right 80°																
Degrees	Degrees																
Left 30°	Right 30°																
Degrees	Degrees																
7. Hip (flexion)		8. Hip (adduction)															
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="text-align: center; padding: 2px;">Left</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Knee Flexed 100°</td> <td style="text-align: center; padding: 2px;">Knee Extended 100°</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Degrees</td> <td style="text-align: center; padding: 2px;">Degrees</td> </tr> <tr> <td colspan="2" style="text-align: center; padding: 2px;">Right</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Knee Flexed 100°</td> <td style="text-align: center; padding: 2px;">Knee Extended 100°</td> </tr> </table>	Left		Knee Flexed 100°	Knee Extended 100°	Degrees	Degrees	Right		Knee Flexed 100°	Knee Extended 100°		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;">Left 20°</td> <td style="text-align: center; padding: 2px;">Right 20°</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Degrees</td> <td style="text-align: center; padding: 2px;">Degrees</td> </tr> </table>	Left 20°	Right 20°	Degrees	Degrees
Left																	
Knee Flexed 100°	Knee Extended 100°																
Degrees	Degrees																
Right																	
Knee Flexed 100°	Knee Extended 100°																
Left 20°	Right 20°																
Degrees	Degrees																

	Degrees	Degrees			
9. Hip (Abduction)		10. Knee (flexion)			
	Left 40°	Right 40°		Left 150°	
	Degrees	Degrees		Degrees	Right 150°
				Degrees	Degrees

DSHS 13-585A (REV. 03/2014)

11. Shoulder (Abduction – Adduction)		12. Shoulder (Flexion – Extension)	
	Left		
	Abduction 150°	Adduction 30°	
	Degrees	Degrees	
	Right		
Abduction 150°	Adduction 30°	Extension 50°	Flexion 150°
Degrees	Degrees	Degrees	Degrees
13. Elbow		14. Forearm (Pronation – Supination)	
	Left		
	Extension 0°	Flexion 150°	
	Degrees	Degrees	
	Right		
Extension 0°	Flexion 150°	Pronation 80°	Supination 80°
Degrees	Degrees	Degrees	Degrees
15. Ankle		16. Ankle (Flexion – Extension)	
	Left		
	Inversion 30°	Eversion 20°	
	Degrees	Degrees	
	Right		
Inversion 30°	Eversion 20°	Plantar 40°	Dorsal 20°
Degrees	Degrees	Degrees	Degrees
17. Wrist (radial, ulnar)		18. Wrist	
	Left		
	Radial 20°	Ulnar 30°	
	Degrees	Degrees	
	Right		
Radial 20°	Ulnar 30°	Extension 60°	Flexion 60°
		Degrees	Degrees

	Degrees	Degrees		Degrees	Degrees
19. Thumb (MP Joint)			20. Thumb (IP Joint)		
	Left	Right		Left	Right
	Flexion 60°	Flexion 60°		Flexion 80°	Flexion 80°
	Degrees	Degrees		Degrees	Degrees
DATE OF EXAMINATION	EXAMINING PHYSICIAN'S SIGNATURE			DATE OF REPORT	

DSHS 13-585A (REV. 03/2014)

APPENDIX G

FACILITIES/SUPPORT

Due West Therapeutic Riding Center

Due West is a Professional Horseman Certified Therapeutic Riding Center equipped with trained staff and certified calm therapy horses. Due West disabilities served include: ADD or other Hyperactivity Disorder, Alzheimer's/Dementia, Amputee, At Risk Youth, Autism, Cerebral Palsy, Developmental Delay or Disability, Down Syndrome, Emotional, Behavioral, or Mental Health, Epilepsy/Seizure Disorders, Genetic Conditions/Disorders, Head Trauma/Brain Injury, Hearing Impairment, Intellectual Disability, Learning Disability, Multiple Sclerosis, Muscular Dystrophy, Orthopedic Issues, Paralysis, PTSD, Speech Impairment, Spina Bifida, Spinal Cord Injury, Stroke, Substance Abuse, Terminal Illness, Violence, Abuse or Trauma, Visual Impairment, Weight Control Disorders. The staff is trained to help with all aspects of therapeutic riding as an intervention.

University of Missouri-Kansas City

The University of Missouri-Kansas City (UMKC) is part of a four-campus University of Missouri System, a land-grant university and Missouri's only public research and doctoral-level institution. Chartered in 1929, UMKC has a diverse enrollment of 15,492 students from nearly every county in Missouri, every state in the nation, and 73 countries. UMKC has an academic health center; the Schools of Nursing and Health Studies, Medicine, Pharmacy, and Dentistry comprise the health sciences disciplines. UMKC is one of fewer than 30 universities nationwide to have nursing, medicine, dentistry, and pharmacy education programs centrally located on one "Hospital Hill" campus. The School of Nursing & Health Studies along with the School of Pharmacy has recently moved to a new, state-of-

the-art Health Sciences Building at the heart of the campus. School of Nursing & Health Studies faculty have established collaborations with researchers from the Schools of Pharmacy, Dentistry and Medicine and with clinical partners at Children's Mercy Hospital and Truman Medical Center, also located on the Hospital Hill campus. The affiliated clinical facilities include Truman Medical Center, Children's Mercy Hospital, and nearly 100 community-wide facilities in the Kansas City metro area. These facilities provide superb research sites and clinical education for undergraduate, graduate, and professional students in the health sciences. UMKC is a stakeholder institution in the Kansas City Area Life Sciences Institute which provides seed money to area researchers and actively supports life sciences research among contributors, legislators, and the business community.

University of Missouri-based Support for Research

The University of Missouri fosters an environment that encourages the pursuit of research and scholarly inquiry. The Office of the Vice Provost for Research oversees the many individual research commitments of the University community and actively promotes such efforts. That office coordinates the integrated research activities and services that thrive in the University of Missouri environment. Further development of the research enterprise remains one of the university's core missions. The University has experience in providing support for large, long-term intervention studies. The grants office at the University has successfully administered large multi-site research projects. UMKC partners with Kansas University on a Clinical Translational Science Institute that houses both basic and clinical research activities and partners with the Stowers Institute for Medical Research to move technology from the bench to the bedside.

University of Missouri Libraries

The mission of the Libraries at the University of Missouri is to support the teaching and research needs of the university community. The library staff provides extensive services, including reference, circulation, reserve reading, interlibrary loan, database searching, a current awareness service, citation verification, tours, and bibliographic and classroom instruction. The Microcomputer Learning Laboratory has computers and laser printers available for faculty, students, and staff.

The University of Missouri Libraries also provide extensive information resources for faculty and student research. Holdings in the University of Missouri library system number 3 million volumes, 6.7 million microforms, and over 22,000 serial titles, many of which are online. There is an extensive collection of federal and state reports and statutes. Online computer database searches are readily available to faculty and students through the World Wide Web. The MU Libraries offer access to Medline, CINAHL, SocioFile, PsycINFO, and other computerized databases.

University of Missouri Health Sciences Library

The Health Sciences Library is located in the School of Medicine adjacent to the School of Nursing and Health Studies. It has a collection of 2,070 volumes and 34 serial titles, and it currently receives numerous print-only periodicals pertaining to medicine, nursing, hospital administration, and related fields. The Library also has access to online periodicals, electronic books, and electronic databases available to patrons from the Library's website. The Library has four professional librarians and four support staff members. The Library is the Missouri Liaison in the National Library of Medicine's National Network of Libraries of Medicine Program, which is a nationwide network of more

than 4,000 health sciences libraries and information centers. The Health Sciences Library purchases a vast number of nursing volumes from all major publishers annually.

Furthermore, the Health Sciences Library honors all faculty requests for new nursing textbooks. It houses a collection of texts on the general topic of nursing alone.

In addition to main and branch libraries on this campus, the University of Missouri System has Health Sciences Libraries at the Columbia and St. Louis campuses. All libraries within the system are full participants in the Libraries of the University of Missouri Network. Lending among the three campuses is very rapid with the efficient daily courier service. Interlibrary loan outside the university system is a readily available service provided by the Health Sciences Library for securing documents not available in the system.

University of Missouri-Kansas City School of Nursing and Health Studies

The School of Nursing and Health Studies (SON&HS) is dedicated to discovering new knowledge and implementing best practices in teaching, research, and service. The SON is committed to preparing nurses at the baccalaureate, masters, and doctoral levels to meet care needs of the citizens of Missouri and beyond. Diversity is embraced among faculty, staff, and students to best prepare future nurses and nurse scientists. The education of persons of diverse ethnic backgrounds is a high priority, and the SON offers fellowships and assistantships to qualified applicants. The SON is in a privileged position to prepare graduates to function in a variety of leadership roles and to advance the body of nursing knowledge. The SON supports the University's broad mission of research, service, extension, and education, including the full range of programs in nursing: Bachelor of Science, Master of Science, Doctor of Nursing Practice, and Doctor of Philosophy.

The School of Nursing and Health Studies embraces the opportunities inherent in being part of a large, progressive health sciences system and a land grant university. The School is committed to creating an intellectually stimulating and culturally diverse environment. Research is a central focus within the SON. Faculty members are deeply committed to generating usable new knowledge about health and the promotion of health over the lifespan; care of persons with health problems and disabilities; nursing systems to promote high quality, cost-effective nursing care; and nursing actions that enhance the ability of individuals to respond effectively to actual or potential health problems.

The SON has received funding for multiple R01s, R03s, R15s, R21s, and R29s within the past ten years. Additional funding from private foundations, state contracts, and external entities further enhance the scholarly mission of the school. The school's research-related environment is thriving.

School of Nursing and Health Studies Office of Research

The Office of Research is devoted to development and utilization of nursing research. This Office is a centralized resource with the overall goal of enhancing the research potential of SON faculty and students. The Office stimulates research-related activities among nursing faculty, staff, and students; encourages interdisciplinary research collaboration; facilitates research collaboration among nursing faculty, students, and practicing clinicians; and assists faculty and student in obtaining external funding for their research endeavors.

A senior faculty member, Dr. Patricia Kelly, serves as Professor and Associate Dean for Research. The Office of Research personnel include a grants specialist, a grant writer, an administrative assistant, a biostatistician, and graduate research assistants. These

individuals consult with faculty on research opportunities, proposal development, research design, statistical analyses and interpretation, computer applications, preparation of data for publication, preparation of manuscripts, and strategies for research utilization. Other administrative staff members assist these personnel, including a grants accountant and the school's business manager.

Institutional Support for the Proposed Project

The School of Nursing and Health Studies provides each faculty member with an office and the necessary support facilities to maintain a professional and productive working environment. Secretarial, copying, and administrative supports for the existing programs are available. Technical support is available through the Division of Information Technology throughout campus, and the School has a full-time computer technical support person for both hardware and software consultation and repair. The SON provides faculty support in the form of photocopying costs, inter-library loan services, Internet access, desktop computer systems, and technical support for research. The SON Research Resource Room contains books, manuals, research instruments, and information on software packages that are used in nursing research.

The University owns and operates a multi-tiered client-server network. It is accessible 24 hours a day through hard-wired work stations on campus or remote dial-up workstations. Faculty and students have access to sufficient file storage facilities. Completely equipped instructional computing laboratories with World Wide Web access are available on campus. Each laboratory is appropriately staffed. Computer application short courses are taught each semester and most are free of charge. SON faculty, staff, and students have access to the electronic LAN system and the client-server architecture. The

School of Nursing has nearly 200 computers for use by faculty, students, and staff in meeting education, research, and support needs. Every faculty member has a personal computer in her or his office. All faculty computers are connected to the Health Sciences System Local Area Network.

APPENDIX H

OPT-IN FORM

Dear _____, (Mr. or Ms. Last Name)

I am writing to tell you about the **HEAT** study being conducted by the Sharon White-Lewis at Saint Luke's College of Health Sciences or Due West Therapeutic Center. We received permission from your care provider [INSERT NAME] to contact you.

The purpose of this research study is to discover the practicality and acceptability of ways of helping arthritic adults.

You may be eligible for this study if you a) have arthritis, b) have stiff or painful joints from your arthritis not controlled by medications or c) have transportation to travel within the Kansas City Metropolitan area.

It is important to know that this letter is not to tell you to join this study. It is your decision. Your participation is voluntary. Whether or not you participate in this study will have no effect on your relationship with [Insert Dr. office] as a patient.

If you are interested in learning more, please review the information below. A researcher will contact you by phone to set up an appointment to discuss the study.

You do not have to respond if you are not interested in this study. If you do not respond, no one will contact you.

Thank you for your time and consideration. We look forward to hearing from you.

Sincerely,

Sharon White-Lewis MSN, RN

Include enclosure(s) as applicable:

Opt-in Form

Opt-in Form (continued)
HEAT STUDY

Please complete this form and return to your healthcare provider if you wish further information

I am interested in learning more about this study. Please contact me using the following information:

Name:

Telephone(s):

Best time and day to
call: _____

Email:

_____@_____

APPENDIX I
SCREENING TOOL

1. Name: _____ (First and Last)
2. Age: _____
3. Race (circle one) White African American Asian American Indian Pacific Islander Hispanic
4. Do you have Osteoporosis (circle one)? Yes No
5. Do you have transportation that you can use once a week? Yes No
6. Have you ridden horses in the last six months? Yes No
7. Do you have a fear of or are you allergic to horses (circle one)? Yes No
8. What is your zip code? _____
9. Current medications (please list by name)
 - a. _____
 - b. _____
 - c. _____
 - d. _____
 - e. _____
 - f. _____
 - g. _____
 - h. _____
 - i. _____
10. Do you see a physician on a regular basis? Yes No
11. What is your arthritis diagnosis?

12. Pain score (See VAS)
13. Goinometer readings (see Range of Joint Motion Evaluation Chart)

APPENDIX J

CONSENT FORMS

EAT

Consent for Participation in a Research Study

Equine-assisted Therapy for Adults and Older Adults with Arthritis IRB 16-276

Principal Investigator: Cynthia L. Russell, PhD RN

Co-Investigator: Sharon White-Lewis MSN, RN

Request to Participate

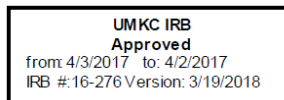
You are being asked to take part in a research study. This study is being conducted at *Due West Therapeutic Riding Center*.

The researcher in charge of this study is *Sharon White-Lewis*. While the study will be run by her, other qualified persons who work with her may act for her. The study sponsor is Saint Luke's College of Health Sciences.

The study team is asking you to take part in this research study because you have arthritis. Research studies only include people who choose to take part. This document is called a consent form. Please read this consent form carefully and take your time making your decision. The researcher or study staff will go over this consent form with you. Ask her to explain anything that you do not understand. Think about it and talk it over with your family and friends before you decide if you want to take part in this research study. This consent form explains what to expect: the risks, discomforts, and benefits, if any, if you consent to be in the study.

Background

- Your arthritis causes you pain and stiffness affecting your ability to move and your quality of life.
- We know that your muscles and cartilage effect these symptoms and that exercise improves the symptoms.
- What we do not know is if these symptoms. We would



riding a horse will improve like to test this.

Purpose:

The purpose of this study is to discover the practicality and acceptability of doing this research project. We also want to find out whether horse riding shows improvement in your arthritis. Previous research studies on adults and children have shown an improvement in cerebral palsy, spinal cord injuries, body mass index, stroke, and balance.

You will be one of about 10 subjects in the study at Due West Therapeutic Riding Center. About 20 subjects total will take part across all the places working on this study.

Study Procedures and Treatments

Screening: This will occur at a place that is convenient for the subject

To know if you meet the requirements to be in this study we will have you complete:

- A survey that helps us understand your pain level - 1 minute
- Measure your shoulders, hips, back and knees to see how far they can bend comfortably– 10 minutes
- Fill out information about your age, race, gender, income, arthritis medication, and approximate years with arthritis – 10 minutes
- A questionnaire on your arthritis, the environment, and your feelings about horses – 3 minutes

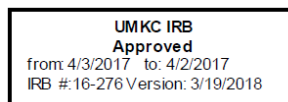
If you agree to take part in this study, you will be involved in this study for 1 -1.5 hours each week for 6 weeks.

If you decide to join in this study:

You will be randomly assigned to 1 of 2 groups for the six week study period. This is similar to flipping a coin. The odds that you will be in the one group or the other is 50% or 1 out of 2.

If you fit the study requirements we will continue at this meeting with:

- Answering any questions that we can
- Have you take 2 more surveys
- Draw a sample of blood (2 teaspoons) will be taken from a vein in your arm to test your muscles and your cartilage
- Provide a map to the Therapeutic Riding Center



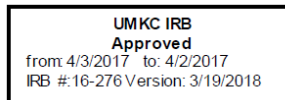
For the study - You will be asked to:

- Wear a protective helmet
- Groom and interact with a horse before and after riding – 10 minutes before and after riding for a total of 20 minutes
- Saddling for 5 minutes before riding and unsaddling for 5 minutes after riding
- Ride a horse for 30 minutes at a walk with helpers on each side and in front of the horse for safety. The entire session will be 60 minutes.
- Take your medication as prescribed during the study
- Talk to Sharon White-Lewis about any problems you are having during the study
- Receive reminder phone calls each week

Study Visit 1

- You will receive reminder phone calls the evening before class
- You will travel to the Therapeutic Riding Center where you will be met by Sharon White-Lewis

- A short tour of the facilities and introductions to any of the staff will occur (10 minutes)
- You will be taken to meet your horse and taught how to groom and prepare the horse (10 minutes) including saddling (5 minutes). Sharon White-Lewis will be with you for help and instructions
- At the first meeting with your horse, Sharon White-Lewis will give you a safety briefing of behaviors to keep you safe and the horse safe (15 minutes).
- It will be recommended that if you take an anti-inflammatory or pain medication when needed, that you take it before your study visits.
- Then you will climb a mounting stairs and get on your horse. The horse will walk while being led through cones and in different patterns such as serpentine, zig-zag, circles and lines for 30 minutes. Assistants will be on either side to maintain your balance and help you stay on the horse if you need it. There will be another assistant leading your horse if you have no experience or you may steer the horse with the reins if you have experience. Thick reins will be provided if you have trouble gripping.
- After the ride you will dismount at the mounting stairs with help from the assistants. You will be asked to stretch your shoulders, hips, back and knees (10 minutes) and brush the horse/unsaddle (5 minutes).
- Total Time: 1.5hours
- You then may return home
- A follow-up phone call will occur the next day



Horse Riding Study Visits 2, 4 and 5

- You will travel to the Therapeutic Riding Center where you will be met by Sharon White-Lewis
- You will be taken to meet your horse, groom and mount just like Study Visit 1.
- When riding the horse will have different patterns each week that include steering through patterns. For safety, the horse will remain at a walk for the duration of this study. Deep breathing and stretching will be added when your balance is sufficient.
- You will then dismount, stretch and groom the horse.
- You may return home.
- Total Time: 1 hour

Horse Riding Study Visits 3 and 6

- The visit will be the same as Study Visits 2, 4, and 5 but measurements, surveys and will occur after the visit. Your blood will be drawn after your Study Visit 6.
- Time for these visits will be 1.5 hours

To be sure that the riding is done in the same way the riding sessions will be watched by a research assistant in the center of the arena.

You will be given written instructions on how to contact any of the researchers in case of problems.

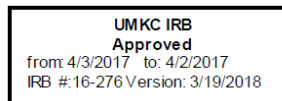
When you are done taking part in this study, you will still have access to the therapeutic riding center and equine-assisted therapy by signing up for sessions. This will be at your own expense and scheduled with Due West Therapeutic Riding Center.

Participation is voluntary and you may refuse to participate in any activities or answer any questions that you wish to at any time. To withdraw from the study you should contact the Principal Investigator Sharon White-Lewis at 913-592-4477. If you withdraw early from the study, you will be asked to complete an end of study visit.

Possible Risks or Side Effects of Taking Part in this Study

Potential risks with the study:

Therapeutic horse-riding is a known safe treatment for children and adults. The only published previous risks include the handlers of the horses being stepped on by the horse (Cook, 2013). The horses are certified therapy horses chosen for proper behavior and tolerance. Although not reported the following are potential risks in riding horses:



- Being kicked by a horse
- Being bitten by a horse
- Sore muscles after riding
- Falling off the horse
- Overstretching or strained muscles and/or joints
- Increased joint pain
- May smell like a barn or horses after treatment

Additional Potential risks with the study:

- Although every attempt will be made to keep records confidential and secure with your identity kept secret, there is always a risk of loss of privacy or breach of confidentiality. All measurements, results, videos will be kept in a locked file cabinet in a locked office with only the Principal Investigator Sharon White-Lewis allowed entry. Your name will be removed from all results and a number assigned to your information. Only the researcher Sharon White-Lewis will have the list of numbers and names associations.
- You may feel uncomfortable about your ability to ride the horse
- You may be embarrassed by the measurement results of your joints ability to move
- You may bruise or have pain at the site of the blood draw
- Transmission of diseases from horses to humans is very rare but possible
- You may feel separation anxiety after you stop riding the horse

Measures to ensure your safety:

- A physician's or Advanced Practice Nurse's release for participation in the study will be obtained

- A Professional Horseman’s Therapeutic Riding Center with experienced staff will administer the riding
- Horses chosen for their calm safe manner that are certified as a therapeutic riding horse will be used
- You will wear a riding helmet when on the horse
- You will receive a safety briefing on Study Visit 1 on how to interact with horses
- Antimicrobial soap will be used prior and after interacting with the horse
- A high step mounting block will be used to mount the horse
- Thick reins will be available for use if deemed desirable by you
- An experienced nurse Sharon White-Lewis will draw your blood
- Drawing blood can cause pain, bleeding, bruising, or swelling where you were stuck with the needle. Sometimes people faint. Getting an infection is rare.
- You will be instructed to take any anti-inflammatory or pain medication that is prescribed as needed during the study



This research is considered to be minimal risk with these safeguards. That means that the risks of taking part in this research study are not expected to be more than the risks in your daily life. There are no other known risks to you if you choose to take part in this study.

Possible Benefits of being in this study:

- A feeling of happiness and well-being
- A feeling of being powerful
- Improved joint range of motion
- Decreased pain and stiffness
- Make friends
- Bond with a horse
- Develop a deeper understanding of your abilities
- Feel that you have helped advance science for adults with arthritis

It is possible that your arthritis may improve with study treatment. It is also possible that the study treatment will not work. Your health problem may not get better or could get worse during this study.

Other people may benefit in the future from the information about equine-assisted therapy that comes from this study.

Costs of being in this study

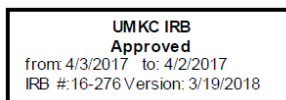
- There will be no cost for the therapeutic riding center or study participation

Compensation

- A \$50 gas gift card will be given at the end of the study
- If you must withdraw from the study before the end of the study a \$25 gift card will be given.

Alternatives to Study Participation

If you decide not to be a part of this study you would follow your doctor's normal course of care with anti-inflammatory or pain medications. If you decide not to participate, information about arthritis exercise options will be given to you along with contact information for the Arthritis Foundation.



Confidentiality and Access to your Records

The results of this research may be published or presented for scientific purposes. You will not be named in any reports of the results. Your study or applicable medical records that have your identity in them may be shown to the Institutional Review Board (IRB) (a committee that reviews and approves research studies), or other governing agencies. This is to prove which study procedures you completed and to check the data reported about you. They may also review your medical records for any treatment you received before you agreed to take part in this study. This is to confirm your medical history and that you meet the requirements to be in this study. The study team will keep all information about you confidential as provided by law but complete confidentiality cannot be guaranteed.

If you leave the study or are removed from the study, the study data collected before you left may still be used along with other data collected as part of the study. For purposes of follow-up studies and if any unexpected events happen, subject identification will be filed at Saint Luke's College of Health Sciences under appropriate security and with access limited to medical research personnel only.

If you sign this consent form, you are allowing the study team and these other agencies to see your medical records.

Confidentiality of Your Information:

- Your results will be kept confidential by assigning a number to you that is only known to the Co-Investigator Sharon White-Lewis and Principal Investigator Cindy Russell. The number assigned to your name will be kept in a locked file cabinet in a locked office with access available to the researchers only. All data will be communicated with the IRB, research assistants, and dissertation chair will be with this number and not your name.
- Information about this study will only be communicated with your permission and in the ways that you allow.
- If you withdraw from the study the information and results will be handled in the same confidential manner.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

UMKC IRB
Approved
from: 4/3/2017 to: 4/2/2017
IRB #:16-276 Version: 3/19/2018

In Case of Injury

If you sustain any injury from this study you will be responsible for the treatment and you will be responsible for covering the costs of that treatment.

Participation in this research study does not take the place of routine physical examinations or clinic visits to your personal physician. If you believe you have been injured as a result of participating in this study you are encouraged to contact the study investigator, Sharon White-Lewis at 913-594477.

The University of Missouri-Kansas City appreciates people who help it gain knowledge by being in research studies. It is not the University's policy to pay for or provide medical treatment for persons who are in studies. If you think you have been harmed because you were in this study, please call the researcher, **Sharon White-Lewis** at **913-592-4477**. She is available 24 hours a day, 7 days a week.

Contacts for Questions about the Study

You should contact the IRB Administrator of UMKC's Adult Health Sciences Institutional Review Board at 816-235-5927 if you have any questions, concerns or complaints about your rights as a research subject. You may call the researcher **Sharon White-Lewis** at **913-592-4477** if you have any questions about this study. You may also call her if any problems come up.

Voluntary Participation

Taking part in this research study is voluntary. If you choose to be in the study, you are free to stop participating at any time and for any reason. If you choose not to be in the study or decide to stop participating, your decision will not affect any care or benefits you are entitled to. The researchers, doctors or sponsors may stop the study or take you out of the study at any time

- if they decide that it is in your best interest to do so,
- if you experience a study-related injury,
- if you need additional or different medication/treatment,
- if you no longer meet the study criteria, or
- if you do not comply with the study plan.

They may also remove you from the study for other administrative or medical reasons. You will be told of any important findings developed during the course of this research.

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from: 4/3/2017 to: 4/2/2017
IRB #:16-276 Version: 3/19/2018

You have read this Consent Form or it has been read to you. You have been told why this research is being done and what will happen if you take part in the study, including the risks

and benefits. You have had the chance to ask questions, and you may ask questions at any time in the future by calling **Sharon White-Lewis at 913-592-4477 or Cynthia Russell at 816-235-2661.**

By signing this consent form, you volunteer and consent to take part in this research study. Study staff will give you a copy of this consent form.

Signature (Volunteer Subject) Date Printed Name (Volunteer Subject)

Signature (Authorized Consenting Party) Date Printed Name (Authorized Consenting Party)

**Relationship of Authorized Consenting
Party to Subject**

Signature of Person Obtaining Consent Date Printed Name of Person Obtaining Consent



Exercise Education Group

Consent for Participation in a Research Study

Exercise Education for Adults and Older Adults with Arthritis

Principal Investigator: Cynthia L. Russell, PhD, RN

Co-Investigator: Sharon White-Lewis MSN, RN

Request to Participate

You are being asked to take part in a research study. This study is being conducted at **Saint Luke's College of Health Sciences**

The researcher in charge of this study is **Sharon White-Lewis**. While the study will be run by her, other qualified persons who work with her may act for her. The study sponsor is Saint Luke's College of Health Sciences.

The study team is asking you to take part in this research study because you have arthritis. Research studies only include people who choose to take part. This document is called a

consent form. Please read this consent form carefully and take your time making your decision. The researcher or study staff will go over this consent form with you. Ask her to explain anything that you do not understand. Think about it and talk it over with your family and friends before you decide if you want to take part in this research study. This consent form explains what to expect: the risks, discomforts, and benefits, if any, if you consent to be in the study.

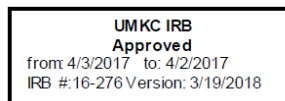
Background

- Your arthritis causes you pain and stiffness affecting your ability to move and your quality of life.
- We know that your muscles and cartilage effect these symptoms and that exercise improves the symptoms.
- What we do not know is if exercise education will improve these symptoms. We would like to test this.

Purpose:

The purpose of this study is to discover the practicality and acceptability of doing this research project. We also want to find out whether exercise education shows better improvement in your arthritis. Previous research studies on adults and children have shown an improvement in arthritis symptoms with proper exercise.

You will be one of about 10
Luke's College of Health



subjects at in the study at Saint
Sciences. About 20 subjects

total will take part across all the places working on this study.

Study Procedures and Treatments

Screening: This will occur at a place that is convenient for the participant

To know if you meet the requirements to be in this study we will have you complete:

- A survey that helps us understand your pain level - 1 minute
- Measure your shoulders, hips, back and knees to see how far they can bend comfortably– 10 minutes
- Fill out information about your age, race, gender, income, arthritis medication, and approximate years with arthritis – 10 minutes
- A questionnaire on your arthritis and the environment – 3 minutes

If you agree to take part in this study, you will be involved in this study for 1 -1.5 hours each week for 6 weeks.

You will be randomly assigned to 1 of 2 groups for the six week study period. This is similar to flipping a coin. The odds that you will be in the one group or the other is 50% or 1 out of 2.

If you fit the study requirements we will continue at this meeting with:

- Answering any questions that we can
- Have you take 2 more surveys

- Draw a sample of blood (2 teaspoons) will be taken from a vein in your arm to test your muscles and your cartilage
- Providing a map to the Educational class

The following study visits and procedures will occur:

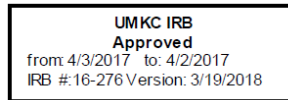
Exercise Education Class:

Study Visit 1

- You will receive reminder phone calls the evening before class
- Please take your normal medication as prescribed
- Travel to and from Saint Luke’s College of Health Sciences
- Attend an exercise education event for 1 hour

Study Visit 2

- You will receive reminder phone calls the evening before class
- Please take your normal medication as prescribed
- Travel to and from Saint Luke’s College of Health Sciences
- Attend an exercise education event for 1 hour



Study Visit 3

- You will receive reminder phone calls the evening before class
- Please take your normal medication as prescribed
- Travel to and from Saint Luke’s College of Health Sciences
- Attend an exercise education event for 1 hour
- After class you will be asked to fill out 2 surveys, rate your pain, have your hips, back, shoulders, and knees measured
- This will take about 30 minutes extra for a total of 1.5 hours for this visit

Study Visit 4

- You will receive reminder phone calls the evening before class
- Please take your normal medication as prescribed
- Travel to and from Saint Luke’s College of Health Sciences
- Attend an exercise education event for 1 hour

Study Visit 5

- You will receive reminder phone calls the evening before class
- Please take your normal medication as prescribed
- Travel to and from Saint Luke’s College of Health Sciences
- Attend an exercise education event for 1 hour

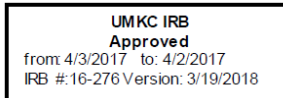
Study Visit 6 (Final Study Visit)

- You will receive reminder phone calls the evening before class

- Please take your normal medication as prescribed
- Travel to and from Saint Luke’s College of Health Sciences
- Attend an exercise education event for 1 hour
- After class you will be asked to fill out 2 surveys, rate your pain, have your hips, back, shoulders, and knees measured
- This visit you will have a sample of blood (2 teaspoons) will be taken from a vein in your arm to test your muscles and your cartilage

You will be provided the class by email or the method

- This will take about 30 hours for this visit



arthritis exercise information from you desire within 3 days minutes extra for a total of 1.5

You will be given written instructions on how to contact any of the researchers in case of problems.

Sharon White-Lewis will meet you and escort you to the education room the first night of class.

- Time for visits 1, 2, 4, and 5 will be 1 hour
- Time for visits 3 and 6 will be approximately 1.5 hours due to surveys and measurements

Participation is voluntary and you may refuse to participate in any activities or answer any questions that you wish to at any time. To withdraw from the study you should contact the Principal Investigator Sharon White-Lewis at 913-592-4477. If you withdraw early from the study, you will be asked to complete an end of study visit.

Possible Risks or Side Effects of Taking Part in this Study

Potential risks with the study:

- Although every attempt will be made to keep records confidential and secure with your identity kept secret, there is always a risk of loss of privacy or breach of confidentiality. All measurements and results will be kept in a locked file cabinet in a locked office with only the Principal Investigator Sharon White-Lewis allowed entry. Your name will be removed from all results and a number assigned to your information. Only the researcher Sharon White-Lewis will have the list of numbers and names associations.
- You may bruise or have pain at the site of the blood draw

Measures to ensure your safety:

- A physician’s or Advanced Practice Nurse’s release for participation in the study will be obtained
- An experienced nurse Sharon White-Lewis will draw your blood
- Drawing blood can cause pain, bleeding, bruising, or swelling where you were stuck with the needle. Sometimes people faint. Getting an infection is rare.

- You will be instructed to take any anti-inflammatory or pain medication that is prescribed as needed during the study

This research is considered to be safeguards. That means that the research study are not expected daily life. There are no other known risks to you if you choose to take part in this study.

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minimal risk with these risks of taking part in this to be more than the risks in your

Possible Benefits of being in this study:

- Better understanding of arthritis
- Better understanding of exercise
- Knowledge about how to exercise with arthritis
- Make friends
- A list of internet sites that have more information on exercise with arthritis
- May have a feeling of being able to improve arthritis problems
- Feel that you have helped advance science for adults with arthritis

It is possible that your arthritis may improve with study treatment. It is also possible that the study treatment will not work. Your health problem may not get better or could get worse during this study.

Costs of being in this study

- There will be no cost for the arthritis education or study participation

You will be responsible for doctor and or hospital costs as usual. You or your insurance company will have to pay for any medical treatment during this study.

Payment for Taking Part in this Study

- A \$50 gas gift card will be given at the end of the study
- If you must withdraw from the study before the end of the study a \$25 gift card will be given.

Alternatives to Study Participation

If you decide not to be a part of this study you would follow your doctor’s normal course of care with anti-inflammatory or pain medications. If you decide not to participate, information about arthritis exercise options will be given to you along with contact information for the Arthritis Foundation.

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Confidentiality and Access to your Records

The results of this research may be published or presented for scientific purposes. You will not be named in any reports of the results. Your study or applicable medical records that

have your identity in them may be shown to the study sponsor Saint Luke's College of Health Sciences, the Institutional Review Board (IRB) (a committee that reviews and approves research studies), or other governing agencies. This is to prove which study procedures you completed and to check the data reported about you. They may also review your medical records for any treatment you received before you agreed to take part in this study. This is to confirm your medical history and that you meet the requirements to be in this study. The study team will keep all information about you confidential as provided by law, but complete confidentiality cannot be guaranteed.

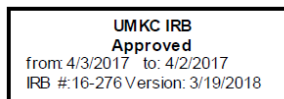
If you leave the study or are removed from the study, the study data collected before you left may still be used along with other data collected as part of the study. For purposes of follow-up studies and if any unexpected events happen, subject identification will be filed at Saint Luke's College of Health Sciences, Sharon White-Lewis' office where records are sealed under appropriate security and with access limited to medical research personnel only.

If you sign this consent form, you are allowing the study team and these other agencies to see your medical records.

Confidentiality of Your Information:

- Your results will be kept confidential by assigning a number to you that is only known to the Co-Investigator Sharon White-Lewis and Principal Investigator Cindy Russell. The number assigned to your name will be kept in a locked file cabinet in a locked office with access available to the researchers only. All data will be communicated with the IRB, research assistants, and dissertation chair will be with this number and not your name.
- Information about this study will only be communicated with your permission and in the ways that you allow.
- If you withdraw from the study the information and results will be handled in the same confidential manner.

A description of this clinical
<http://www.ClinicalTrials.gov>,
Web site will not include
At most, the Web site will include a summary of the results. You can search this Web site at any time.



trial will be available on
as required by U.S. Law. This
information that can identify you.

In Case of Injury

If you sustain any injury from this study you will be responsible for the treatment and you will be responsible for covering the costs of that treatment. Participation in this research study does not take the place of routine physical examinations or clinic visits to your personal physician. If you believe you have been injured as a result of

participating in this study you are encouraged to contact the study investigator, Sharon White-Lewis at 913-592-4477.

The University of Missouri-Kansas City appreciates people who help it gain knowledge by being in research studies. It is not the University’s policy to pay for or provide medical treatment for persons who are in studies. If you think you have been harmed because you were in this study, please call the researcher, *Sharon White-Lewis* at *913-592-4477*. She is available 24 hours a day, 7 days a week.

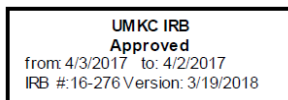
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Voluntary Participation

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- if you do not comply with the study plan.



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By signing this consent form, you volunteer and consent to take part in this research study. Study staff will give you a copy of this consent form.

Signature (Volunteer Subject)

Date

Printed Name (Volunteer Subject)

Signature (Authorized Consenting Party)

Date

Printed Name (Authorized Consenting Party)

**Relationship of Authorized Consenting
Party to Subject**

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent

UMKC IRB
Approved
from: 4/3/2017 to: 4/2/2017
IRB #:16-276 Version: 3/19/2018

APPENDIX K

H.E.A.T. STUDY

PROTOCOL IMPEDIMENT/VIOLATION FORM

Please describe any impediments, roadblocks, issues you have observed concerning the study protocol:

- Issues with protocol that were resolved (If reason is known, please state the reason):

- Issues with protocol that could not be completed (If reason is known, please state the reason):

- Issues with protocol compliance (defined as a refusal or inability to comply with the study protocol):

APPENDIX L
EXIT SURVEYS

EAT Group

H.E.A.T. STUDY

Exit Survey

Please circle your response. There is no right or wrong answer.

1. Do you intend to continue with the therapeutic riding at your own expense? Yes No
2. Studies that test a new treatment often have a second group to compare the treatment with. Were you in the treatment group or the control group? Treatment Control
3. Do you feel the time spent each session was: Too long Too short Just right
4. Do you feel that the time spent in the overall study was: Too long Too short Just right
5. Do you think that the amount of measurements (surveys, blood drawn, joint measurements) were too many? Yes No
6. Do you have any other suggestions to improve this study?

H.E.A.T. STUDY
EXIT SURVEY

Exercise Education Group

Please circle your response. There is no right or wrong answer.

1. Do you intend to start an exercise program after you are finished with this study?
Yes No

2. Studies that test a new treatment often have a second group to compare the treatment with. Were you in the treatment group or the control group? Treatment Control

3. Do you feel the time spent each session was: Too long Too short Just right

4. Do you feel that the time spent in the overall study was: Too long Too short Just right

5. Do you think that the amount of measurements (surveys, blood drawn, joint measurements) were too many? Yes No

6. Do you have any other suggestions to improve this study?

APPENDIX M

ENGEL'S BIOPSYCHOSOCIAL CONCEPT – DEPENDENT VARIABLES

Biopsychosocial Concept	Variable	Measurement	Reliability/Validity	Collected
Person	Range of Motion	Goniometer Physiologic - Hips, back, knee, shoulder	Reliability good to excellent 0.79–0.97; (Fieseler et al., 2015) Reliability \geq 0.94 and validity \geq 0.85 (Kolber & Hanney, 2012)	0, 3, and 6 weeks
Nervous System	Pain	Visual Analog Scale Physiologic - Hips, back, knee, shoulder	Reliability Moderate to good higher among literate ($r=0.94$, $P=0.001$) than illiterate patients ($r=0.71$, $P=0.001$) Validity varied from 0.16 to 0.51; (Boonstra et al., 2008) Construct validity is highly correlated to a 5 point scale (0.71–0.78) and a numeric scale (0.62–0.91); (G.A. Hawker, Mian, Bednis, & Stanaitis, 2011)	0, 3, and 6 weeks
Cell/Tissue	Muscle	Biomarker Troponin Biologic - Blood	None found	0 and 6 weeks
Cell/Tissue	Cartilage	Biomarker Cartilage Oligomeric Matrix Protein Biologic - Blood	(Felson & Lohmander, 2009); (Mayeux, 2004)	0 and 6 weeks
Cultural/subculture	Quality of life	AIMS-2 Social/Psychological	Reliability 0.78–0.94; (Meenan et al., 1992)	0, 3, and 6 weeks
Biosphere	Enjoyment of Environment	Environmental Attitudes Inventory Scale Subscale #1 Environment	(Milfont & Duckitt, 2010) High test re-test reliability .72-.89 Enjoyment of Nature reliability .79 Validity	0, 3, and 6 weeks

APPENDIX N

ENVIRONMENTAL ATTITUDE INVENTORY SCALE – ENJOYMENT OF NATURE

Please read each question and place an X under your response

I am NOT the kind of person who loves spending time in wild, untamed wilderness areas	Strongly Agree	Agree	Agree Somewhat	Undecided	Disagree Somewhat	Disagree	Strongly Disagree
I really like going on trips into the countryside, for example to forests or fields	Strongly Agree	Agree	Agree Somewhat	Undecided	Disagree Somewhat	Disagree	Strongly Disagree
I find it very boring being out in wilderness areas	Strongly Agree	Agree	Agree Somewhat	Undecided	Disagree Somewhat	Disagree	Strongly Disagree
Sometimes when I am unhappy, I find comfort in nature	Strongly Agree	Agree	Agree Somewhat	Undecided	Disagree Somewhat	Disagree	Strongly Disagree
Being out in nature is a great stress reducer for me	Strongly Agree	Agree	Agree Somewhat	Undecided	Disagree Somewhat	Disagree	Strongly Disagree

(Milfont & Duckitt, 2010)

APPENDIX O
 PROTOCOL STEPS

Screening Visit

	Time Required	Event
Introductions, Initial Study Information, Consenting	1 hour	Introduce the research assistant, principal investigator and the participant - Explanation of study, time requirements, and consenting
Demographics	10 minutes	Demographic information about age, race, gender, income, arthritis medication, and approximate years of arthritis
Screening Measurement of Pain	5 minute	Visual Analog Scale - Inclusion will be considered with a mild [Mild pain (0-44 mm)] to moderate pain level [moderate pain (45-74 mm)]
Screening Measurement of Range of Motion	15 minutes	Measurement of the shoulders, hips, back and knees to see range of motion documented on the Range of Joint Motion Evaluation Chart Decreased range of motion by 20% measured by a goniometer using the Range of Joint Motion Evaluation Chart (In Appendix F)
Review of screening tool answers and medications	10 minutes	It will be recommended that he/she take any pain medication prescribed by his/her physician when exercise is expected.
Questions and answers	20 minutes	Participants' questions will be received and answered
Total	2 hours	

Protocol for the Equine-assisted Therapy Intervention Group

Study Visit	Time Required	Procedure
#1	2 hours	<p>Orient to stables, people, and paperwork. Obtain verbal consent and answer any questions, take measurement. Safety briefing. Introduce human to horse, groom, stretch, and ride</p> <ul style="list-style-type: none"> • Participant will travel to the Therapeutic Riding Center where he/she will be met by Sharon White-Lewis (PI). • A short tour of the facilities and introductions to any of the staff will occur. • The participant will be taken to a room to complete a survey, have his/her blood drawn, and measurements of his/her shoulders, hips, back and knees taken by the principle investigator. • Then he/she will be taken to meet his/her horse and taught grooming, preparation of the horse (10 minutes), including saddling of his/her horse coached by PT or PATH-certified instructor (5 minutes). The saddle is an intentionally light pad used for therapeutic riding that allows the heat of the horse to penetrate to the rider. • At the first meeting with his/her horse, a safety briefing will occur (see Safety Briefing in Appendix P). • The participant will climb a mounting stairs and mount the horse. Care will be taken not to stretch or stress the joints during mounting. The horse will remain at a walk while being led through cones and in different patterns such as serpentine, zig-zag, circles, and lines for 30 minutes. Assistants stay on either side to maintain his/her balance and help him/her stay on the horse. There will be another assistant leading the horse if the participant has no experience or he/she may steer the horse with the reins if he/she has experience. Thick reins will be provided if the participant has difficulty gripping. • After the 30-minute ride the participant will dismount at the mounting stairs with help from the assistants. He/she will be asked to stretch his/her shoulders, hips,

		<p>back and knees for 10 minutes and brush the horse/unsaddle for 5 minutes.</p> <ul style="list-style-type: none"> • A follow-up phone call will occur the next day.
#2, 4 and 5	1 hour	<p>Groom, stretch, and ride</p> <ul style="list-style-type: none"> • The participant will travel to the Therapeutic Riding Center and be escorted to the riding area. • He/she will be taken to meet the horse, groom, and mount just like Study Visit #1. • Riding will include steering the horse through different patterns each week. For safety, the horse will remain at a walk for the duration of this study. Deep breathing and stretching on the horse will be added when the participant's balance is sufficient to progress. • The participant will then dismount, stretch, and groom the horse.
#3 and 6	1.5 hours	<p>Groom, stretch, ride, and complete surveys and measurements</p> <ul style="list-style-type: none"> • The visit follows the same protocol as Study Visits 2, 4, and 5 except measurements, surveys, and blood draws will occur after the visit.
Total	8 hours	<p>Extra time may be needed in Week #6 for good-byes and ending discussions.</p>

Exercise Education Attention-Control Group Protocol

Study Visit	Time Required	Procedure
#1	1.5 hours	<p>Orient to classroom, people, and paperwork. Obtain verbal consent and answer any questions.</p> <ul style="list-style-type: none"> • Travel to Johnson County Orthopedics at the predetermined time and day. PI will meet the participant and escort him/her the first night to the education classroom. • An education class will be delivered by the PI: Exercise for patients with arthritis (see Appendix E) - one hour.

		<ul style="list-style-type: none"> • Before the class week #1 and after class weeks 3 and 6, the participant will complete surveys, have blood drawn, and measure his/her shoulders, hips, back and knees. • Handouts and information about exercise for arthritis are given. • No additional exercise during the six-week study period is required.
#2, 4 and 5	1 hour	<ul style="list-style-type: none"> • Travel to designated education site and room at the predetermined time and day. • An education class is delivered on exercise for patients with arthritis – one hour.
#3, and 6	1.5 hours	<ul style="list-style-type: none"> • Travel to designated education site and room at the predetermined time and day. • Participants will complete surveys, have blood drawn, and measure his/her shoulders, hips, back and knees.
Total	8 hours	Extra time may be needed in Week #6 for good-byes and ending discussions

APPENDIX P
SAFETY TRAINING
(USPC Safety Committee, 2017)

CHAPTER III: Unmounted Safety

One of the wonderful things about horses is that they have a mind of their own. However, because they can think independently of the humans around them, and because the horse's natural reaction to threats is to flee, this also means that there are some important things to keep in mind in order to keep both humans and horses safe during equestrian activities.

WORKING WITH A HORSE ON THE GROUND

Be Aware

Even the calmest horse may startle. When working with horses it is helpful to keep in mind their range of vision. Horses see best about 55–65 degrees directly in front of them, with a small blind spot in the very center of their forward visual field. They have more limited (monocular) sight to the side. A horse can see very little of what happens behind them, so must rely on sound to determine what is approaching or happening to their rear.

It is never a good idea to stand directly in front of a horse. If a horse is startled it may move forward quickly. Standing to one side of the horse will keep you from getting run over.

Approaching a Horse

Try to approach from the front or side of a horse. This way the horse knows you are not a threat.

Sometimes when a horse is tied, you may need to approach them from the rear. Use your voice as a cue so that they know where you are, and give them time to react before you are in range of any startled behavior.

Leading a Horse

Most horses can be lead from either side. It is more common to lead from the left or near side of the horse. When doing so, make sure to keep both hands on the lead rope. Your right hand should be about six inches from the snap, your left should hold the folded extra length.

- Never hold loops of lead rope. Fold it to avoid being entangled should your horse spook.
- Never tie or wind the lead rope around any part of you in any way.
- Do not put the excess lead rope over your shoulder.
 - If the horse spooks, the rope could whip around your neck, dragging you along behind your frightened horse.
- Always turn a horse away from you while leading.

- Always hold the cloth portion of the lead rope (never the metal chain) if using a chain shank.
- If a chain is used, it must be threaded over the horse's nose or attached to the halter in another safe way, so neither you nor your horse can become tangled in the chain.

Tying a Horse

- The object the horse is tied to must be sturdy enough to withstand the horse setting back against it.
 - Example: use a fencepost rather than a rail. Never tie to a temporary stall or a stall door.
- When tying to a trailer, you must have a tow vehicle attached to the trailer.
 - This gives the trailer more stability so that if a horse pulls back, the trailer will not tip over.
 - If bad weather hits, you can load your horse immediately without spending valuable time hooking up the tow vehicle.
- While both cotton and nylon are appropriate choices for lead ropes and cross ties, keep in mind that nylon creates more friction on the hand than cotton does, which means a greater chance of rope burn.
 - Never use a bungee-style tie. When a horse sets back and the tie comes loose, it acts as a missile, springing back toward either you or the horse.
- What has the horse's history been with tying? If he has had issues in the past with pulling back, then perhaps having someone hold the horse while working with him is a better choice.
- Always use a quick release knot when tying with a lead rope to a fixed object.
- When a horse is tied, do not duck under the horse's neck to get to the other side. It is much safer to go around the rear of the horse.
 - Put a hand on the horse's hip to let him know when you are going around the hind end. Walk close to the horse, with a hand on the hindquarters to let him know you are there, or walk far enough away to avoid the hooves should the horse kick out.

CHAPTER III: Unmounted Safety

- When tying in cross ties, make certain that the end attached to the fixed post has a breakaway option, either a safety string or panic snap.
 - Cross ties should be at the level of the horse's back.
- If you are working with your horse in cross ties in a barn aisle and someone needs to lead another horse by, unsnap one of the ties and move your horse to the side. Never lead a horse under a fastened cross tie.
- Horses should not be left unattended in cross ties. They could get bored or startled and hurt themselves—or you.
- Untie the lead rope/cross ties before putting halter around neck when bridling and unbridling. This is more secure should the horse try to pull away.
- Secure the halter up off the ground after bridling. If you leave it hanging on the ground, it becomes a tripping hazard.
- Keep tie area clear of hazards—don't leave your grooming kit where it can be stepped on or nibbled.

SAFE ATTIRE WHEN WORKING WITH HORSES

Since any horse may spook at any time, it is important to make sure that you are wearing proper footwear. According to the Horse Management Handbook and Rules for Rallies, (7c), proper footwear must meet all the following criteria:

- Thick-soled shoes/boots (short or tall)
- Cover the ankle
- In good condition
- Made of leather or synthetic materials
- Entirely closed
- Securely fastened
- Well-fitted to foot
- Sturdy construction

Example: paddock boots

Gloves are required for longeing, are recommended while riding, and can save a handler from blisters or worse when working with a horse on the ground.

In addition, it is best to wear clothes that fit properly. Loose clothing can snag on objects and too-tight clothing can limit movement.

UNMOUNTED LONGE WORK:

See section on Longeing in **CHAPTER FOUR: Riding Safety.**

CHAPTER IV: Riding Safety

Riding lore has it that jumping, racing and Western speed events are the most dangerous of horse sports, but accident studies both in the United States and England show that most accidents result with horses on pleasure rides going no faster than the walk.

CHOOSING A MOUNT

Choosing a mount is one of the more stressful things Pony Club parents are asked to do. Wouldn't it be wonderful if we only had to do it once? Beginners and young riders need friendly, well-mannered mounts. Trying to make one mount meet the changing needs of the rider can mean compromising safety.

So what do we look for? First, realistically assess the rider and his/her abilities. A young or novice rider needs a mount that is friendly, quiet, and unflappable. Far too many accidents occur when handling unruly ponies. The rider and mount need to fit each other physically, too. A horse that is either too large or too small can make the rider less secure. Unfortunately, a pony can be outgrown in a very short period of time (see, D Manual Second edition; pp 15-21).

"Learning together" is NOT a good idea with a sport as potentially dangerous as riding. Well-schooled mounts are often expensive, but are probably worth it. Looking in other disciplines for a well-trained mount with good temperament can be a good compromise when looking for Pony Club mounts. Older horses can be excellent teachers. The horse must be sound enough to safely perform the required tasks. Having a realistic discussion with the veterinarian at a pre-purchase exam, including an honest discussion of the type of work likely to be expected of the horse, will help decide if that horse is a good fit for that rider doing that activity.

Judgment is required to determine if a particular horse or horse/rider combination is unsafe. If Pony Club members do show up on unsuitable mounts, it is the responsibility of leadership to obtain input from knowledgeable horse persons and act on it. No one wants to be the 'bad guy,' but if an unsafe situation exists, it must not be allowed to continue.

Horses are large, unpredictable animals and riding is a high-risk sport. Pony Club represents participating in this wonderful sport as safely as possible. Buying the safest, most appropriate mount you can afford is one way to reduce the risks. A cheap horse is not always a bargain! Anyone who has owned horses knows the purchase price is a small part of the total investment. A sane, safe beginner mount will always be in demand when you need to move up to a bigger or more athletic animal for your advancing Pony Club member.

RIDING ATTIRE

Helmet/Proper Helmet Fit:

Wearing an approved helmet every ride, every time is the only smart thing to do. See Helmet Requirements & Fitting (Excerpted from HM Handbook and Rules for Rallies, Appendix G).

From Attachment A to USPC Policy 0800—Safety Requirements for Helmets:

The United States Pony Clubs, Inc. recognizes that riding is an inherently dangerous equestrian sport and consideration of safety is of extreme importance. Participating in any equine activity can result in injury or death and as a result individuals must assume responsibility for their own safety.

Wearing a properly fitted equestrian helmet, securely fastened, containing certification that it meets or exceeds the criteria established by the following international or national safety bodies is required to participate in any Pony Club activities:

- American Society for Testing Materials (ASTM)
- European Normes (EN)
- British (PAS)
- Australian/New Zealand (AS/NZ)

To preserve optimal function and lifespan of a helmet, avoid placing it in contact with hairspray, sunscreen or insect repellents. Clean the inside and outside of the helmet often with warm water and a mild detergent. DO NOT soak any part of the helmet, put it close to high heat, or use strong cleaners. Helmets should be stored in a room that does not get too hot or too cold and where it is away from direct sunlight. (Do not store an equestrian helmet in a car).

It is important to check helmets for damage and NOT allow a rider to use a cracked or broken helmet or a helmet that is missing any padding or parts. Replace any equestrian helmet that is damaged or has been involved in an impact from a fall. Equestrian helmets are designed to help protect the rider's brain and head from only one serious impact. You may not be able to see the damage to the foam, but the foam materials in the helmet will crush after an impact. That means that the foam in the helmet can't help protect the rider's brain and head from another impact.

Footwear:

Having a thousand pound animal step on your instep is painful. Worse, it can break bones that may never heal. Wear proper footwear.

From the Horse Management Handbook and Rules for Rallies, 7f:

A conventional type of riding footwear with a heel is required. (e.g., leather, synthetic or rubber riding boots, paddock/Jodhpur boots or equivalent). "Waffle" type soles are not permitted.

CHAPTER IV: Riding Safety

RIDING SAFETY

Before Mounting a Horse

Prior to every mounted meeting each member must have a "pre-ride inspection" or Safety Check.

The Safety Check will include a check of the member's equipment, including correct attire and proper adjustment and condition of tack, and a check of the mount that is being used. Knowledgeable adults may be assigned to assist the instructor(s) in conducting Safety Checks prior to the start of the meeting.

No member is ever responsible for another member's safety. C-1 Certified or above members may do Safety Checks under the supervision of a knowledgeable adult.

Refer to Appendix E for a safety checklist.

Riding in the Open

As open land inevitably disappears, more and more pleasure riders, including Pony Club members attending Pony Club activities, are going to have to negotiate roads.

All riders must learn to share the road with other users in a safe, courteous, and pleasurable way. Riding outside a ring—along trails and field—can be great fun and a nice change for you and your mount. To enjoy it fully, however, you must learn the rules that will keep you safe. A knowledgeable rider follows these rules and shows respect for the land he or she is privileged to ride on.

Before You Ride In the Open:

- Before attempting to ride in the open, a rider should feel confident at the walk, trot and canter and have basic control of his or her mount.
- Before mounting, make use of the Safety Check Checklist to ensure tack, horse and rider are properly outfitted for the ride. (See Appendix H, pg 30.)
- Never ride alone.
- Make sure at least one experienced rider goes along. When riding in a large group, the most experienced rider should be in the lead, the least experienced in the middle, and a strong rider in the rear.
- Let someone know where you will be riding.
- Know and follow your state's traffic laws as they apply to horses. Remember that you must obey the instruction of Police Officers or other appointed persons engaged in controlling traffic. Your State Department of Motor Vehicles will supply you with a Driver's Manual that explains the Highway Code.
- Find out if you or your horse is likely to be considered liable if you cause any harm to other people or their

property. Your insurance carrier can tell you this.

- Make sure you can control your horse in traffic. If you have a green horse or one that you know is traffic-shy, go on the road only in the company of steady horses. Better yet, keep to quiet roads and avoid peak traffic times until your horse has learned to accept oncoming or passing cars and trucks.
- When riding in groups, plan the ride with the least experienced horse or rider in mind and be considerate of other riders.
- Avoid riding at night.
- Check with property owners in advance to make sure their land is open to you.
- Be aware of any horse that might kick. Tie a red ribbon as a warning on his tail and put him at the end of the line.

While Riding in the Open

- Be prepared for the unexpected at all times.
- Walk for at least the first ten minutes and the last ten minutes. When it is cold, you may increase this time to fifteen minutes so that horses are adequately warmed up and cooled off.
- Before changing the gait, the leader should warn the group and give time for preparation.
- Stay behind one another so your horse's head is facing the tail of the horse in front of you. Ride in single file. Do not pass without specific permission from the group leader; if a horse needs to pass (after permission has been given) turn your horse's head towards the passing rider to prevent any kicking.
- Distances (the faster you are going the longer it takes to stop):
 - At walk, keep one horse's length between you and the horse in front.
 - At the trot, two horses' lengths.
 - At the canter, three horses' lengths.
- Starting with the leader, every second rider should warn those behind of dangers ahead. Do not hold branches, as they will snap back in the face of the next rider.
- If a car passes, it is better to keep your horse moving at a controlled speed. A stopped horse is concentrating on the oncoming car. A moving horse being asked to continue walking has most of his attention on the rider and less on the passing traffic.
- When it is necessary to cross a highway, use a flanking movement, where all the horses turn and cross the road at the same time rather than crossing single file. After crossing, no one should proceed until all other riders are

The conversation between the rider and the person providing the Safety Check can serve as an important education moment for less experienced riders and serves as a complimentary second check for someone with more experience.

RIDER:

- Pinnie or rider number if at Rally
- Medical release in armband or medical bracelet.
- Helmet—Contains certification by one of the following international or national safety bodies (ASTM, EN, CE, PAS, AS/NZ, ISO), properly fitted, securely fastened and in good condition. Hair away from face and rider number.
- No jewelry that dangles except medic alerts. Stud piercings, wedding rings, show bows and decorated stock pins allowed.
- Safe, neat, workmanlike attire. (Shirt tucked in, belt, if there are loops except for Games and UR-D2).
- Safe and conventional footwear with a heel.
- Whips or bats correct size for discipline with no wrist loops.

MOUNT:

- Well groomed in accordance with rider's certification level.
- Check condition of feet, if picked out, shoes and studs (if any) secure and suitable for ground condition.
- Galls, cuts, or other wounds attended to.

BRIDLE:

- Check overall fit and all stitching for signs of wear and condition of leather.
- Cavesson/Noseband—should be 1-2 fingers below cheekbone, snug but not uncomfortably tight.
- Keepers, buckles and hooks—secured and in good condition.
- Cheek pieces—should be of equal length with at least 1 spare hole above the buckle.
- Crown piece/Brow band—fit without rubbing or pinching ears
- Throatlatch—loose enough for the neck to flex, tight enough so it can't be pulled over cheekbones. There should be a fist or 4 fingers between the throatlatch and the throat. At least 1 spare hole above buckle.
- Dropped nosebands—should rest on edge of nose bone, just above the soft part of the nose, snugly, yet be able to slip a finger underneath
- Flash noseband—cavesson should be adjusted fairly high and snugly. The flash strap should not pull the cavesson down. The chinstrap/flash strap should fit snugly below the bit, in the chin groove with the buckle not near the lips.

- Figure 8 noseband—The upper strap goes under the jaw behind the cheekbones, inside the bridle. The lower strap buckles below the bit, in the chin groove. The small pad rests high on the nose bone, where the straps cross. Both straps should be snug, but not tight.

- Reins—Check at bit and buckle for signs of wear, Check stitching and length.

BIT:

- Check for correct adjustment and size, 1/4" space on each side is recommended depending on type of bit and shape of horses' mouth.
- Check for rough spots and rust.
- Snaffle—typically 2 small wrinkles at corners of lips. Cheek pieces do not bow away from face when reins are tightened.
- Pelham and Kimberwickes—typically one small wrinkle at corners of lips.
- Curb Chain—Twisted so links are flat and adjusted so that when the bit rotates 45 degrees the curb chain comes into contact with the chin groove to tighten chain.
- Lip Strap—runs through the center (fly) link and buckles to tiny rings on bit shank

SADDLE:

- Check overall fit, tree, condition and cleanliness of leather and stitching
- Safety bar is down/open
- Stirrup leathers—Check soundness of buckles, leather, and stitching. They should be an appropriate length, and at least two spare holes above and one below the buckle.
- Stirrup irons—Appropriate size, 1" wider than rider's boot. Metal not stressed or bent. Pads in good condition, not worn/hard. They should fit snugly in the stirrup. Fillis stirrups must have pads. Peacock rubbers in good condition, not split or rotten.
- Buckle/billet guards—Required except for saddles with long billets. They should cover the buckles.
- Girth—Check for cleanliness and wear. It should have at least two buckles on each end. It should be adjusted the same on each side with at least two holes above the buckle and one below when the girth is tightened. Saddle pad strap goes through one/two of the billet straps.
- Billets—The first billet must be used, but using either the second or third billet is acceptable depending on the fit.
- Saddle pad—Same on both sides, smooth, pulled up into the gullet and off the withers.

APPENDIX Q
DATA ANALYSIS

Primary Questions

RQ1) What is the feasibility of adults and older adults with arthritis attending a six-week equine-assisted therapy program compared with an exercise education attention control group? Descriptive statistics

RQ1a To what extent can we recruit participants to take part in the study?

RQ1b To what extent can the intervention procedures be implemented correctly?

RQ1c To what extent can we maintain adequate fidelity with the intervention?

RQ1d Does the recruitment procedure sequence produce study participants?

RQ1e How many meet excluded criteria?

RQ1f What is the attrition?

RQ1g To what extent are the measurements completed?

RQ 1h Were the measurements able to be performed within the designated time?

RQ 1i Do the participants comply with the intervention?

RQ 1j How much data is missing?

RQ2) For adults and older adults with arthritis, what is the acceptability of the study protocol with equine-assisted therapy as the intervention? Descriptive statistics and theme generation.

Specific Aim: To measure the acceptability of the study protocol with equine-assisted therapy as the intervention and exercise education as the control.

RQ2a Do the study participants intend to continue the intervention after the end of the study?

RQ2b Do the participants stay in the assigned groups, e.g., not wanting to move from control group to treatment group?

RQ2c Do participants know that they are in the treatment group or control group at the end of the study?

RQ 2d Do the participants feel the time spent per session is too long, too short, or just right?

RQ2e Do the participants feel the time spent in the study (six weeks) was too long, too short or just right?

RQ2f Do the participants feel the measurements were too extensive?

RQ2g Any other comments about the study?

Exploratory Questions

RQ1) Research question: What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on pain in adults and older adults with arthritis? (Outcome measuring pain – visual analog scale)

IV: Equine-assisted therapy

DV: Pain

Level of Measurement: Ordinal (pain scale)

Statistical test: For the within group data were calculated by Friedman's statistical test since the level of measurement is ordinal and between groups it would be Mann Whitney U. The small sample size requires non-parametric statistical methods since the data were not normally distributed.

RQ2) Research question: What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on range of motion in adults and older adults with arthritis?

(Outcome measuring range of motion - goniometer)

IV: Equine-assisted therapy

DV: Goniometer

Level of Measurement: Ratio

Statistical test: For the within group data were calculated by Friedman's statistical test since the level of measurement is ordinal and between groups it would be Mann Whitney U. The small sample size requires non-parametric statistical methods since the data were not normally distributed.

RQ3) Research question: What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on a troponin biomarker for muscle in adults and older adults with arthritis? (Outcome measuring biomarker)

IV: Equine-assisted therapy

DV: Biomarker Cartilage Oligomeric Matrix Protein biomarker

Level of Measurement: Ratio

Statistical test: For the within group data were calculated by Friedman's statistical test and between groups it would be Mann Whitney U. The small sample size requires non-parametric statistical methods since the data were not normally distributed.

RQ4) What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on Cartilage Oligomeric Matrix Protein biomarker for cartilage in adults and older adults with arthritis? (Outcome measuring biomarker)

IV: Equine-assisted therapy

DV: Biomarker Cartilage Oligomeric Matrix Protein biomarker

Level of Measurement: Ratio

Statistical test: For the within group data were calculated by Friedman's statistical test I and between groups it would be Mann Whitney U. The small sample size requires non-parametric statistical methods since the data were not normally distributed.

RQ5) Research question: What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on quality of life in adults and older adults with arthritis? (Outcome measuring quality of life – Arthritis Impact Measurement Scale 2)

IV: Equine-assisted therapy

DV: Quality of Life

Level of Measurement: Ordinal

Statistical test: For the within group data were calculated by Friedman's statistical test since the level of measurement is ordinal and between groups it would be Mann Whitney U. The small sample size requires non-parametric statistical methods since the data were not normally distributed.

RQ6) Research question: What is the effect of an equine-assisted therapy intervention compared with an exercise attention-control intervention on enjoyment of nature in adults and older adults with arthritis? (Outcome measuring enjoyment of nature – Environmental Attitudes Inventory Scale – Subscale #1)

IV: Equine-assisted therapy

DV: Quality of Life

Level of Measurement: Ordinal

Statistical test: For the within group data were calculated by Friedman's statistical test since the level of measurement is ordinal and between groups it would be Mann Whitney U. The

small sample size requires non-parametric statistical methods since the data were not normally distributed.

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VITA

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Ms. White-Lewis intends to continue her research targeting human-animal interactive methods to alleviate human suffering. Further research includes mobile EAT interventions, miniature horse therapy, and disease transmission between animals and humans on a global scale.